Αποστάγματα από το ACR & το EULAR

Επιλογές από τα σημαντικότερα θέματα που παρουσιάσθηκαν στα Συνέδρια του ACR & της EULAR το 2012

"highlights"

Σπύρος Ν Νίκας
Ρευματολόγος
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5ο ΠΑΝΕΛΛΗΝΙΟ ΕΠΙΣΤΗΜΟΝΙΚΟ ΣΥΜΠΟΣΙΟ
Με διεθνή συμμετοχή

«Η αντιμετώπιση των μυοσκελετικών παθήσεων με βάση τις πραγματικές ανάγκες και τις οικονομικές δυνατότητες»

Σύγκρουση συμφερόντων (Conflict of interest)

Καμία για αυτήν την παρουσίαση

Εκπαιδευτικές-ερευνητικές-συμβουλευτικές επιχορηγήσεις την τελευταία διετία:

Amgen-GSK, MSD, Abbvie

- Μελέτες
- EULAR & ACR 2012
- Κλινική σημασία / καθημέρα κλινική πράξη

"Head to head" μελέτες

“Head to head” μελέτες

- *[LB0003] TOCILIZUMAB MONOTHERAPY IS SUPERIOR TO ADALIMUMAB MONOTHERAPY IN REDUCING DISEASE ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS: 24-Week Data From the Phase 4 ADACTA Trial. Gabay C, Emery P, van Vollenhoven R, et al.*

- *[OP0022] ABATACEPT SC VERSUS ADALIMUMAB ON BACKGROUND METHOTREXATE IN RA: ONE YEAR RESULTS FROM THE AMPLE STUDY M. Schiff, R. Fleischmann, M. Weinblatt, R. Valente, D. van der Heijde, G. Citera, C. Zhao, M. Maldonado*

- *[THU0151] EFFECTS OF TOFACITINIB (CP-690,550), AN ORAL JANUS KINASE INHIBITOR, OR ADALIMUMAB ON PATIENT REPORTED OUTCOMES IN A PHASE 3 STUDY OF ACTIVE RHEUMATOID ARTHRITIS. R.F. van Vollenhoven, G. Wallenstein, E.B. Lee, R. Fleischmann, S.H. Zwillich, D. Gruben, T. Koncz, J. Bradley, B. Wilkinson, V. Strand*

“Head to head” μελέτες

Annual European Congress of Rheumatology
6 - 9 JUNE 2012
Berlin
eular2012

EULAR12-5765

TOCILIZUMAB (TCZ) MONOTHERAPY IS SUPERIOR TO ADALIMUMAB (ADA) MONOTHERAPY IN REDUCING DISEASE ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA): 24-WEEK DATA FROM THE PHASE 4 ADACTA TRIAL

C. Gabay [1,*], P. Emery [2], R. van Vollenhoven [3], A. Dikranian [4], R. Alten [5], M. Klearman [6], D. Musselman [6], S. Agarwal [6], J. Green [7], A. Kavanaugh [8]

[1]Univ Hospitals of Geneva, Geneva, Switzerland, [2]Univ Leeds, Leeds, United Kingdom, [3]Karolinska Inst, Stockholm, Sweden, [4]San Diego Arthritis Med Clin, San Diego, United States, [5]Univ Berlin, Berlin, Germany, [6]Genentech, S San Francisco, United States, [7]Roche, Welwyn, United Kingdom, [8]Univ California, San Diego, United States

EULAR12-5765

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Figure 1. DAS28 over time

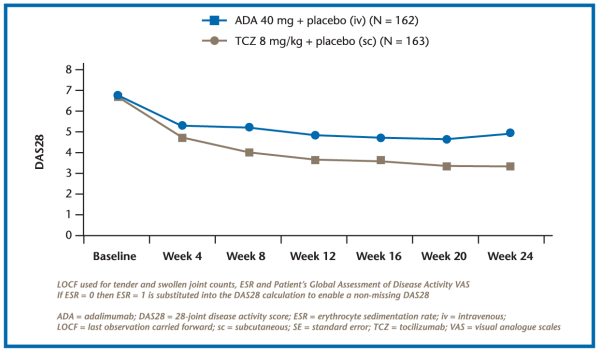
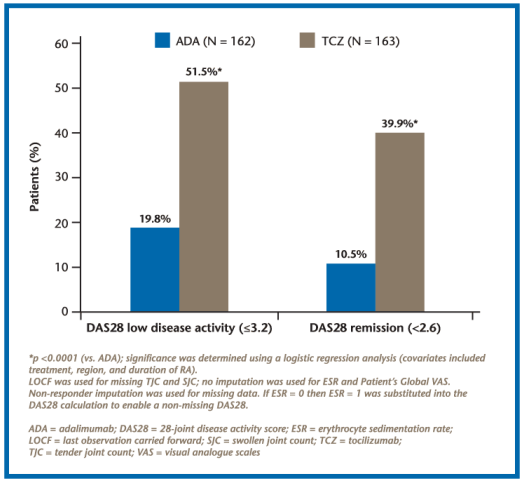


Figure 2. Secondary endpoints (proportions of patients with DAS28 remission/low disease activity at week 24)



Μείωση DAS28:

- -3,3 TOC
- -1,8 ADA

ύφεση:

- 39.9% TOC
- 10,5 % ADA

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- Η συχνότητα των ΑΕ ήταν ίδια και στις 2 ομάδες
- Σοβαρές ανεπιθύμητες ενέργειες & λοιμώξεις επίσης ίδιες
  - tocilizumab: 11.7%, 3.1%
  - adalimumab: 9.9%, 3.1%
- Transaminase , LDL αυξήσεις, και μείωση ουδετεροφίλων
  - Και στις 2 ομάδες
  - Πιο συχνά στην ομάδα υπο tocilizumab

“Head to head” μελέτες

[2012] [OP0022] ABATACEPT SC VERSUS ADALIMUMAB ON BACKGROUND METHOTREXATE IN RA: ONE YEAR RESULTS FROM THE AMPLE STUDY

M. Schiff[1], R. Fleischmann[2], M. Weinblatt[3], R. Valente[4], D. van der Heijde[5], G. Citera[6], C. Zhao[7], M. Maldonado[7] [1]University of Colorado, Denver, CO; [2]University of Texas Southwestern Medical Center, Dallas, TX; [3]Brigham and Women's Hospital, Boston, MA; [4]Arthritis Center of Nebraska, Lincoln, NE, United States; [5]Leiden University Medical Center, Leiden, Netherlands; [6]Instituto de Rehabilitación Psicofísica de Buenos Aires, Buenos Aires, Argentina; [7]Bristol-Myers Squibb, Princeton, NJ, United States

Berlin 6-9 JUNE 2012

[2012] [OP0022] ABATACEPT SC VERSUS ADALIMUMAB ON BACKGROUND METHOTREXATE IN RA: ONE YEAR RESULTS FROM THE AMPLE STUDY

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- Φάση IIIb
- 24 μήνες (12)
- 646 ασθενείς
  - 125 mg **SC** abatacept (χωρίς IV load) εβδομαδιαία
  - 40 mg SC adalimumab /2 εβδ

Berlin
6-9 JUNE 2012

[2012] [OP0022] ABATACEPT SC VERSUS ADALIMUMAB ON BACKGROUND METHOTREXATE IN RA: ONE YEAR RESULTS FROM THE AMPLE STUDY

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- Στον 1ο χρόνο (ITT analysis) ACR 20 απόκριση :
  - 64.8% of ABA ασθενείς
  - 63.4% of ADA ασθενείς
- Ο ρυθμός μη ακτινολογικής εξέλιξης ήταν παρόμοιος
- Παρόμοιος αριθμός ΑΕ, ΣΑΕ, κακοηθειών , σοβαρών λοιμώξεων
- Διαφορές :
  - αυτοανοσία (ABA)
  - διακοπή θεραπείας (ADA)
  - τοπική αντίδραση (ADA)

“Head to head” μελέτες

[2012] [THU0151] EFFECTS OF TOFACITINIB (CP-690,550), AN ORAL JANUS KINASE INHIBITOR, OR ADALIMUMAB ON PATIENT REPORTED OUTCOMES IN A PHASE 3 STUDY OF ACTIVE RHEUMATOID ARTHRITIS

R.F. van Vollenhoven[1], G. Wallenstein[2], E.B. Lee[3], R. Fleischmann[4], S.H. Zwillich[2], D. Gruben[2], T. Koncz[5], J. Bradley[2], B. Wilkinson[2], V. Strand[6] [1]Karolinska Institute, Stockholm, Sweden; [2]Pfizer Inc, Connecticut, United States; [3]Seoul National University, Seoul, Republic of Korea; [4]Metroplex Clinical Research Center, Dallas, Texas; [5]Pfizer Inc, New York; [6]Stanford University, Palo Alto, California, United States

Arthritis & Rheumatism, Volume 63, November 2011 Abstract Supplement

Abstracts of the American College of Rheumatology/Association of Rheumatology Health Professionals Annual Scientific Meeting
Chicago, Illinois November 4-9, 2011.

ues

Tofacitinib (CP-690,550), An Oral Janus Kinase Inhibitor, Or Adalimumab Versus Placebo In Patients With Rheumatoid Arthritis On Background Methotrexate: A Phase 3 Study.

Van Vollenhoven[1], R.F., Fleischmann[2], R. M., Cohen[3], S. B., Lee[4], E. B., Meijide[5], G., Wagner[6], S., Forejtova[7], S.

[2012] [THU0151] EFFECTS OF TOFACITINIB (CP-690,550), AN ORAL JANUS KINASE INHIBITOR, OR ADALIMUMAB ON PATIENT REPORTED OUTCOMES IN A PHASE 3 STUDY OF ACTIVE RHEUMATOID ARTHRITIS

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- 12-μήνες φάση III
- (RCT) με RA (≥6 TJC/SJC; ESR >28 mm/h or CRP >7 mg/L) και αποτυχία MTX τυχαιοποίηση (4:4:4:1:1)
- 5 θεραπευτικές επιλογές:
  - tofacitinib 5 mg ή
  - 10 mg BID
  - adalimumab 40 mg (SC)
  - PBO advanced to tofacitinib 5 mg BID
  - PBO advanced to tofacitinib 10 mg BID
- Όλοι οι ασθενείς υπό MTX

[2012] [THU0151] EFFECTS OF TOFACITINIB (CP-690,550), AN ORAL JANUS KINASE INHIBITOR, OR ADALIMUMAB ON PATIENT REPORTED OUTCOMES IN A PHASE 3 STUDY OF ACTIVE RHEUMATOID ARTHRITIS

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PRO[a]	PBO[c]	Tofacitinib	Tofacitinib	Adalimumab
% of pts reporting improvements ≥MCID[b]	n=46	5 mg BID	10 mg BID	40 mg Q2W
[MCID values]		n=127	n=134	n=125
PtGA	-12.48	-28.63***	-29.02***	-26.00**
% pts reporting ≥MCID [-10]	*62.37*	*70.11*	*72.38*	*70.56*
Pain (VAS)	-16.34	-30.68***	-31.38***	-27.25**
% pts reporting ≥MCID [-10]	*64.52*	*72.41*	*74.59*	*69.27*
Physical function (HAQ-DI)	-0.33	-0.66***	-0.68***	-0.57**
% pts reporting ≥MCID [-22]	*56.99*	*71.84**	*77.35***	*74.44**
left" colspan="5"]HR-QoL (SF-36)				
Physical Component Score	4.72	8.52**	8.81***	7.25*
% pts reporting ≥MCID [2.5]	*72.04*	*68.21*	*70.00*	*71.51*
Mental Component Score	0.89	5.51**	6.00***	3.93*
% pts reporting ≥MCID [2.5]	*30.11*	*58.38****	*59.44****	*51.96***
Fatigue (FACIT-F)	1.92	6.99***	7.85***	6.47**
% pts reporting ≥MCID [4]	*45.65*	*57.23*	*67.40***	*55.56*
Sleep (MOS Sleep Scale; overall sleep)	-4.14	-12.47**	-12.13**	-10.26*

Η αποτελεσματικότητα του tofacitinib (5 ή 10 mg) ήταν ανώτερη του placebo
Και ίση με το adalimumab

CERTOLIZUMAB στην ΨΑ

[2012] [LB0001] EFFECT OF CERTOLIZUMAB PEGOL ON SIGNS AND SYMPTOMS IN PATIENTS WITH PSORIATIC ARTHRITIS: 24 WEEK RESULTS OF A PHASE 3 DOUBLE BLIND RANDOMIZED PLACEBO-CONTROLLED STUDY (RAPID-PSA)

P.J. Mease[1], R. Fleischmann[2], A. Deodhar[3], J. Wollenhaupt[4], D. Kielar[5], F. Woltering[6], C. Stach[6], B. Hoepken[6], T. Arledge[7], D. van der Heijde[8] [1]Swedish Medical Center and University of Washington, Seattle; [2]University of Texas SW Medical Center, Dallas; [3]Oregon Health & Science University, Portland, United States; [4]Schoen Klinik, Hamburg, Germany; [5]UCB Pharma, Brussels, Belgium; [6]UCB Pharma, Monheim am Rhein, Germany; [7]UCB Pharma, Raleigh, United States; [8]Department of Rheumatology, Leiden University Medical Centre, Leiden, Netherlands

Berlin 6-9 JUNE 2012

[2012] [LB0001] EFFECT OF CERTOLIZUMAB PEGOL ON SIGNS AND SYMPTOMS IN PATIENTS WITH PSORIATIC ARTHRITIS: 24 WEEK RESULTS OF A PHASE 3 DOUBLE BLIND RANDOMIZED PLACEBO-CONTROLLED STUDY (RAPID-PSA)

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- 1η ανακοίνωση για Certolizumab pegol και ΨΑ
- 409 ασθενείς , με αποτυχία σε 1 DMARD ή βιολογικό (20%)
- Φάσης III / 6μήνες
- Δόση εφόδου 400 και μετά
  - 200/2εβδ ή
  - 400 mg / 4 εβδ , για 24 εβδομάδες

Berlin 6-9 JUNE 2012

[2012] [LB0001] EFFECT OF CERTOLIZUMAB PEGOL ON SIGNS AND SYMPTOMS IN PATIENTS WITH PSORIATIC ARTHRITIS: 24 WEEK RESULTS OF A PHASE 3 DOUBLE BLIND RANDOMIZED PLACEBO-CONTROLLED STUDY (RAPID-PSA)

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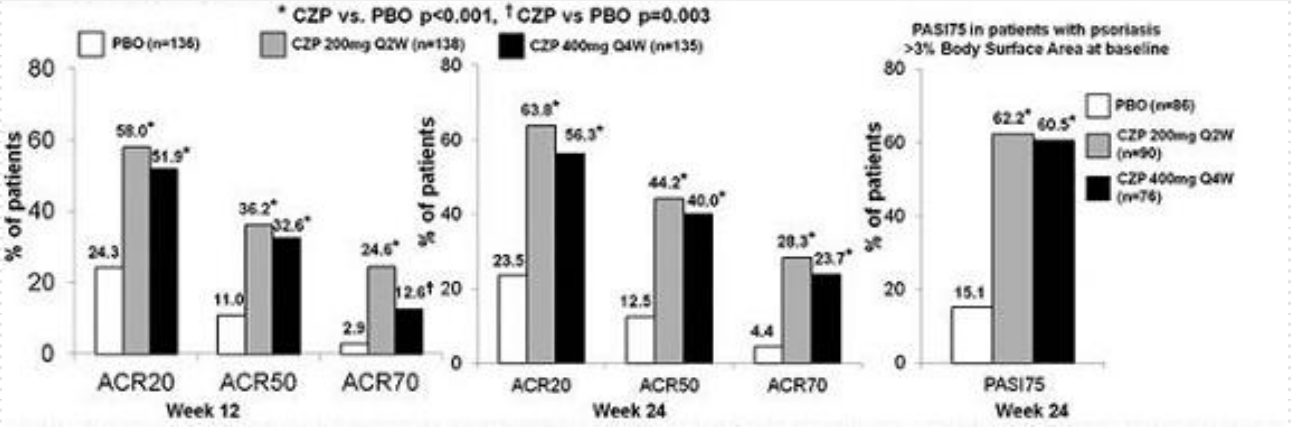

- Βελτίωση σημείων & συμπτωμάτων αρθρίτιδας (ACR20), λειτουργικότητας (HAQ-DI) και δερματικών εκδηλώσεων
- ταχεία δράση
- Προφίλ ασφάλειας : παρόμοιο της PA

Stelara στην ΨΑ

[2012] [OP0158] USTEKINUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: RESULTS OF THE PHASE 3, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED PSUMMIT I STUDY

I.B. McInnes[1], A. Kavanaugh[2], A.B. Gottlieb[3], L. Puig[4], P. Rahman[5], C. Ritchlin[6], S. Li[7], Y. Wang[7], A.M. Mendelsohn[7], M.K. Doyle[7,8], on behalf of the PSUMMIT I Study Group [1]U Glasgow, Scotland, United Kingdom; [2]U California, San Diego, CA; [3]Tufts Med Cntr, Boston, MA, United States; [4]Universitat Autònoma de Barcelona, Barcelona, Spain; [5]Memorial U, NL, Canada; [6]U Rochester, Rochester, NY; [7]Janssen R&D, Spring House, PA; [8]U Penn, Philadelphia, PA, United States

Berlin 6-9 JUNE 2012

[2012] [OP0158] USTEKINUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: RESULTS OF THE PHASE 3, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED PSUMMIT I STUDY

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- Πολυκεντρική, διπλά-τυφλή ελεγχόμενη με placebo , φάσης III μελέτη
- Ενεργός ΨΑ – 615 ασθενείς
- 45mg, 90mg, ή PBO στις εβδομάδες 0, 4, και ανα 12 εβδ

[2012] [OP0158] USTEKINUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: RESULTS OF THE PHASE 3, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED PSUMMIT I STUDY

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Table: Efficacy Results at Wk 24

	PBO(n=206)	UST45mg(n=205)	UST90mg(n=204)
ACR20, %	22.8	42.4 [p<0.001]	49.5
ACR50, %	8.7	24.9 [p<0.001]	27.9
ACR70, %	2.4	12.2 [p<0.001]	14.2
DAS28-CRP response, %	34.5	65.9 [p<0.001]	67.6
Median HAQ-DI change from BL	-0.0	-0.3 [p<0.001]	-0.3
Pts with ≥0.3 reduction, %	28.2	47.8 [p<0.001]	47.5
PASI75*, %	11.0	57.2 [p<0.001]	62.4
Median % change in enthesitis score*	0.0	-42.9 [p=0.002]	-50.0
Median % change in dactylitis score*	0.0	-75.0 [p<0.001]	-70.8

*Among pts affected at BL.; p<0.001 for all parameters vs PBO

- Σημαντικές διαφορές μεταξύ UST vs PBO , σε ACR, HAQ, PASI75, ενθεσίτιδα, δακτυλίτιδα
- AE : παρόμοιες (λοιμώξεις 2%)
- Η παρουσία MTX δεν τροποποιούσε το αποτέλεσμα

Citation: Ann Rheum Dis 2012;71(Suppl3):107

MTX στην ΨΑ ?

[2012] [OP0160] RESPONSE AND DRUG SURVIVAL OF 1ST TNF INHIBITOR IN 370 PATIENTS WITH PSORIATIC ARTHRITIS IN A REAL LIFE SETTING – WHAT IS THE ROLE OF CO-MEDICATION WITH METHOTREXATE?

K.M. Fagerli[1], E. Lie[1], D. van der Heijde[2], M.S. Heiberg[1], S. Kalstad[3], E. Rodevand[4], K. Mikkelsen[5], Å. S. Lexberg[6], T.K. Kvien[1] [1]Department of Rheumatology, Diakonhjemmet Hospital, Oslo, Norway; [2]Department of Rheumatology, Leiden University Medical Center, Leiden, Netherlands; [3]Department of Rheumatology, University Hospital of Northern Norway, Tromsø; [4]Department of Rheumatology, St. Olavs Hospital, Trondheim; [5]Lillehammer Hospital of Rheumatic Diseases, Lillehammer; [6]Department of Rheumatology, Drammen Hospital, Drammen, Norway

Three-month states and responses were similar between the groups

improved 3-year drug survival in the combination group (p=0.04)

MTX στην ΨΑ ?

A randomized placebo-controlled trial of MTX in PsA

Gabrielle H. Kingsley[1,2], Anna Kowalczyk[1], Helen Taylor[1], Fowzia Ibrahim[1], Jonathan C. Packham[3], Neil J. McHugh[4], Diarmuid M. Mulherin[5], George D. Kitas[6], Kuntal Chakravarty[7], Brian D. M. Tom[8], Aidan G. O'Keeffe[8], Peter J. Maddison[9] and David L. Scott[1,10]

IV Golimumab

Washington, D.C. ACR/ARHP 12 Scientific Meeting
Pre-Conference Courses: November 9-10, 2012
Annual Scientific Sessions: November 10-14, 2012

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Intravenous Golimumab Inhibits Radiographic Progression and Maintains Clinical Efficacy and Safety in Patients with Active Rheumatoid Arthritis Despite Methotrexate Therapy: 1-Year Results of a Phase 3 Trial.

Michael Weinblatt[1], Clifton O. Bingham III[2], Alan Mendelsohn[3], Lenore Noonan[3], Shihong Sheng[3], Lilianne Kim[3], Kim Hung[3], Jiandong Lu[3]. Daniel Baker[3] and Rene Westhovens[4], [1]Rheumatology & Immunology, Brigham & Women's Hospital, Boston, MA, [2]Johns Hopkins University, Baltimore, MD, [3]Janssen Research & Development, LLC, Spring House, PA, [4]University Hospital KU Leuven, Leuven, Belgium

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Intravenous Golimumab Inhibits Radiographic Progression and Maintains Clinical Efficacy and Safety in Patients with Active Rheumatoid Arthritis Despite Methotrexate Therapy: 1-Year Results of a Phase 3 Trial. Michael Weinblatt[1], Clifton O. Bingham III[2], Alan Mendelsohn[3],

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- 1 χρόνος, φάσης III
- IV golimumab (GLM) 2mg/kg+MTX vs placebo στις εβδομάδες :0-4 και ανα 8
- 592 ασθενείς με ενεργό PA

812

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Table: Summary of efficacy among randomized pts. Data shown are number (%) of pts or mean±SD / median (interquartile range)

	Placebo + MTX (n=197)	GLM 2mg/kg + MTX (n=395)
CLINICAL EFFICACY		
Week 14		
ACR20*/ACR50/ACR70	49 (24.9%)/17 (8.6%)/6 (3.0%)	231 (58.5%)/118 (29.9%)/49 (12.4%)***
DAS28-CRP moderate or good response	79 (40.1%)	321 (81.3%)***
Improvement from baseline in HAQ score	0.50 ± 0.58 / 0.13 (-0.13, 0.50)	0.19 ± 0.56 / 0.50 (0.13, 0.88)***
Week 24		
ACR 20 response	62 (31.5%)	248 (62.8%)***
ACR 50 response	26 (13.2%)	142 (35.9%)***
ACR 70 response	8 (4.1%)	69 (17.5%)***
DAS28-CRP moderate or good response	88 (44.7%)	331 (83.8%)***
Improvement from baseline in HAQ score	0.21± 0.55 / 0.13 (-0.13, 0.50)	0.53 ± 0.64 / 0.50 (0.13, 0.88)***
Improvement in HAQ≥0.25 from baseline	89 (45.2%)	266 (67.3%)***
Week 52		
ACR20 response	121 (61.4%)	260 (65.8%)
ACR50 response	62 (31.5%)	153 (38.7%)
ACR70 response	29 (14.7%)	72 (18.2%)
DAS28-CRP moderate or good response	149 (75.6%)	321 (81.3%)
Improvement from baseline in HAQ score	0.42 ± 0.59 / 0.38 (-1.1; 1.9)	0.51 ± 0.65 / 0.38 (-1.0; 2.5)
Improvement in HAQ≥0.25 from baseline	123 (62.4%)	253 (64.1%)
RADIOGRAPHIC PROGRESSION		
Baseline Total vdHS		
Total score	50.26 ± 59.85 / 29.00 (8.50, 77.24)	47.59 ± 54.63 / 28.00 (9.00, 67.50)
Erosion subscore	25.63 ± 32.38 / 13.00 (4.00, 36.00)	23.89 ± 29.00) / 13.50 (4.00, 32.00)
Joint space narrowing subscore	24.63 ± 29.47 / 12.50 (4.00, 37.50)	23.70 ± 28.26 13.00 (3.00, 35.50)
Total vdHS Change from baseline at wk24		
Total score	1.09 ± 3.19 / 0.00 (0.00, 1.49)	0.03 ± 1.90 / 0.00 (-0.50, 0.50)***
Erosion subscore	0.53 ± 2.09 / 0.00 (0.00, 0.50)	-0.12 ± 1.15 / 0.00 (-0.50, 0.00)***
Joint space narrowing subscore	0.56 ± 1.73 / 0.00 (0.00, 0.50)	0.14 ± 1.33 / (0.00, 0.00)**
Proportions of pts at wk24		
Progression based on smallest detectable change (SDC)		
Total (SDC=1.91)	38 (19.3%)	34 (8.6%)***
Erosion (SDC=1.57)	21 (10.7%)	15 (3.8%)***
Joint space narrowing (SDC=1.19)	34 (17.3%)	39 (9.9%)**
Change in vdHS ≤ 0	113 (57.4%)	279 (70.6%)***
Total vdHS change from wk24-wk 52#		
	0.12 ± 2.44 / 0.00 (-0.50, 0.50)	0.15± 1.83 / 0.00 (-0.50, 0.50)
Total vdHS change from wk0-wk52	1.22± 3.98 / 0.00 (0.00, 1.50)	0.13 ± 3.11 / 0.00 (-0.50, 0.50)***

*Primary endpoint, **, ***p-value vs. placebo + MTX < 0.01, 0.001, respectively.
#Pts with missing total vdHS score at wk24 were excluded.

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- GLM+MTX-tx pts μικρότερη ακτινολογική εξέλιξη (total vdHS+subscores) vs PBO+MTX at wk24

- wk14 : (p<0.001) μεγαλύτερο ποσοστό GLM+MTX vs PBO+MTX pts πέτυχαν ACR20, DAS28-CRP good/moderate , ACR50 and ACR70 απόκριση και μεγαλύτερη μέση βελτίωση στο HAQ score (0.50vs0.13)

- AEs and σοβαρές AEs παρατηρήθηκαν στο 65% και 9% των GLM-tx pts (vs 43% και 4% στην 24εβδ)

  - wk52, το ποσοστό των εγχύσεων ήταν 0.7%
  - των ασθενών με *αντίδραση στην έγχυση* και 3.6%
  - (vs 1.1% and 3.5% στην wk24)

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2545

A Randomized, Double-Blind, Parallel Group Study of the Safety and Efficacy of Tocilizumab SC Versus Tocilizumab IV, in Combination with Traditional Dmards in Patients with Moderate to Severe RA.

G. R. Burmester[1], Andrea Rubbert-Roth[2], Alain G. Cantagrel[3], Stephen Hall[4], Piotr Leszczynski[5], Daniel Feldman[6], Madura J. Rangaraj[7], Georgia Roane[8], Charles L. Ludivico[9], Francesco Ramirez[10] and Min Bao[11]. [1]Charité-Universitätsmedizin Berlin, Berlin, Germany, [2]Klinikum der Universität zu Köln, Köln, Germany, [3]Centre Hospitalier Universitaire de Toulouse, Toulouse, France, [4]Cabrini Medical Centre, Malvern, Australia, [5]Hospital J. Strusia, Poznan, Poland, [6]Universidade Federal de de São Paulo, Sao Paulo, Brazil, [7]Arthritis & Diabetes Clinic, Monroe, LA, [8]Rheumatology Associates, P.A., Charleston, SC, [9]East Penn Rheumatology Assoc, Bethlehem, PA, [10]Roche Products Limited, Welwyn, United Kingdom, [11]Genentech, South San Francisco, CA

5ο ΠΑΝΕΛΛΗΝΙΟ ΕΠΙΣΤΗΜΟΝΙΚΟ ΣΥΜΠΟΣΙΟ

Με διεθνή συμμετοχή

«Η αντιμετώπιση των μυοσκελετικών παθήσεων με βάση τις πραγματικές ανάγκες και τις οικονομικές δυνατότητες»

Anti-TNF-α Vs συνδυαστικής αγωγής

[2012] [OP0155] ADDITION OF INFLIXIMAB COMPARED WITH ADDITION OF SULFASALAZINE AND HYDROXYCHLOROQUINE TO METHOTREXATE IN EARLY RHEUMATOID ARTHRITIS: 2-YEAR QUALITY OF LIFE RESULTS OF THE RANDOMISED, CONTROLLED SWEFOT TRIAL

J.A. Karlsson[1], M. Neovius[2], J.-Å. Nilsson[1], I.F. Petersson[1], J. Bratt[3], R.F. van Vollenhoven[3], S. Ernestam[3], P. Geborek[1] [1]Department of Clinical Sciences Lund, Section of Rheumatology, Lund University, Lund; [2]Department of Medicine, Clinical Epidemiology Unit, Karolinska Institutet; [3]Department of Medicine, Rheumatology Unit, Karolinska Institutet, Stockholm, Sweden

[2012] [OP0155] ADDITION OF INFLIXIMAB COMPARED WITH ADDITION OF SULFASALAZINE AND HYDROXYCHLOROQUINE TO METHOTREXATE IN EARLY RHEUMATOID ARTHRITIS: 2-YEAR QUALITY OF LIFE RESULTS OF THE RANDOMISED, CONTROLLED SWEFOT TRIAL

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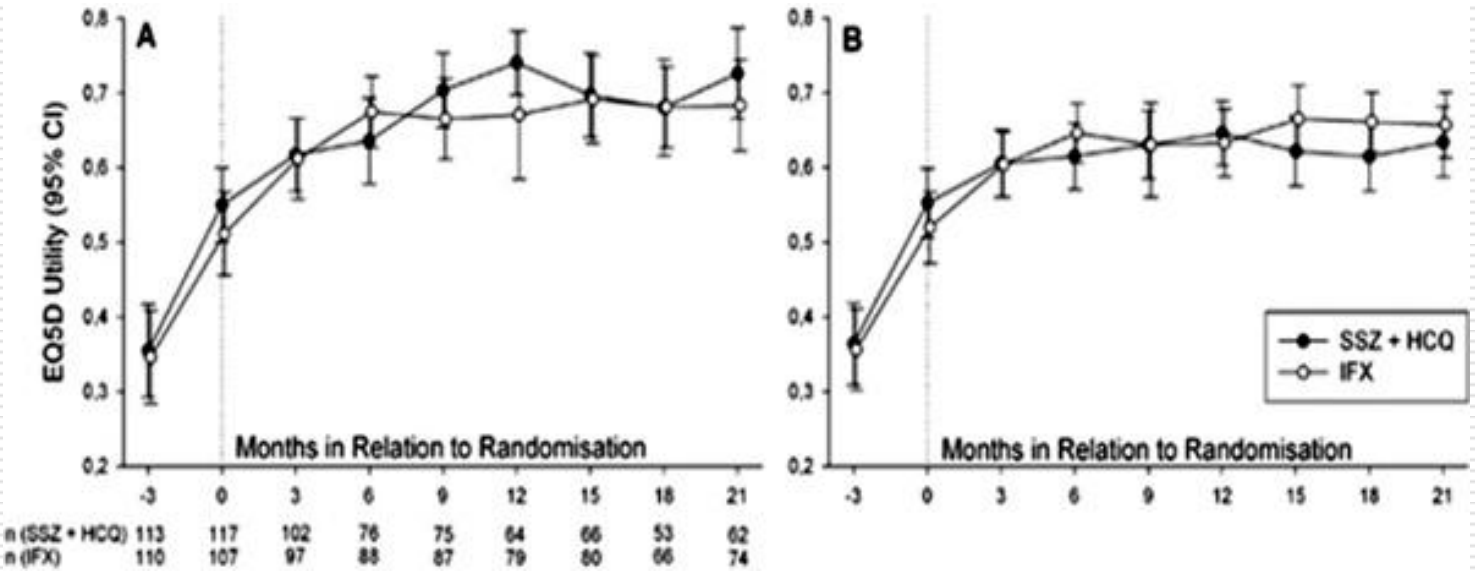
Berlin 6-9 JUNE 2012
eular2012



ΔΕΝ υπήρχαν διαφορές στη βελτίωση του QALY
μεταξύ των 2 ομάδων

771

Discontinuation of Adalimumab without Functional and Radiographic Damage Progression After Achieving Sustained Remission in Patients with Rheumatoid Arthritis (the HONOR study): 1-Year Results. Yoshiya Tanaka, Shintaro Hirata, Shunsuke Fukuyo, Masao Nawata, Satoshi Kubo, Kunihiro Yamaoka and Kazuyoshi Saito. University of Occupational and Environmental Health, Japan, Kitakyushu, Japan

771

Discontinuation of Adalimumab without Functional and Radiographic Damage Progression After Achieving Sustained Remission in Patients with Rheumatoid Arthritis (the HONOR study): 1-Year Results. Yoshiya Tanaka, Shintaro Hirata, Shunsuke Fukuyo, Masao Nawata, Satoshi Kubo, Kunihiro Yamaoka and Kazuyoshi Saito. University of Occupational and Environmental Health, Japan, Kitakyushu, Japan

- Ασθενείς με DAS28-ESR<2.6 για 6 μήνες
  - 197 patients άρχισαν ADA
  - 69 (35.0%) πληρούσαν τα κριτήρια για ύφεση
  - 51 ασθενείς εισήλθαν στη μελέτη
  - 42 τελικά εκτιμήθηκαν ασθενείς
  - 36% έμειναν σε ύφεση χωρίς ADA για 1 χρόνο

- 36% (DAS28-ESR) και 49% (SDAI) ασθενών θα μπορούσαν να διακόψουν το ADA για > 12 μήνες χωρίς λειτουργική επιβάρυνση ή ακτινολογική εξέλιξη

Maintenance, reduction, or withdrawal of etanercept after treatment with etanercept and methotrexate in patients with moderate rheumatoid arthritis (PRESERVE): a randomised controlled trial.
Smolen JS, Nash P, Durez P, Hall S, Ilivanova E, Irazoque-Palazuelos F, Miranda P, Park MC, Pavelka K, Pedersen R, Szumski A, Hammond C, Koenig AS, Vlahos B.
Lancet. 2013 **Mar 16** ;381(9870):918-29. doi: 10.1016/S0140-6736(12)61811-X

5ο ΠΑΝΕΛΛΗΝΙΟ ΕΠΙΣΤΗΜΟΝΙΚΟ ΣΥΜΠΟΣΙΟ

Με διεθνή συμμετοχή

«Η αντιμετώπιση των μυοσκελετικών παθήσεων με βάση τις πραγματικές ανάγκες και τις οικονομικές δυνατότητες»

MTX στην PA

EULAR 2012

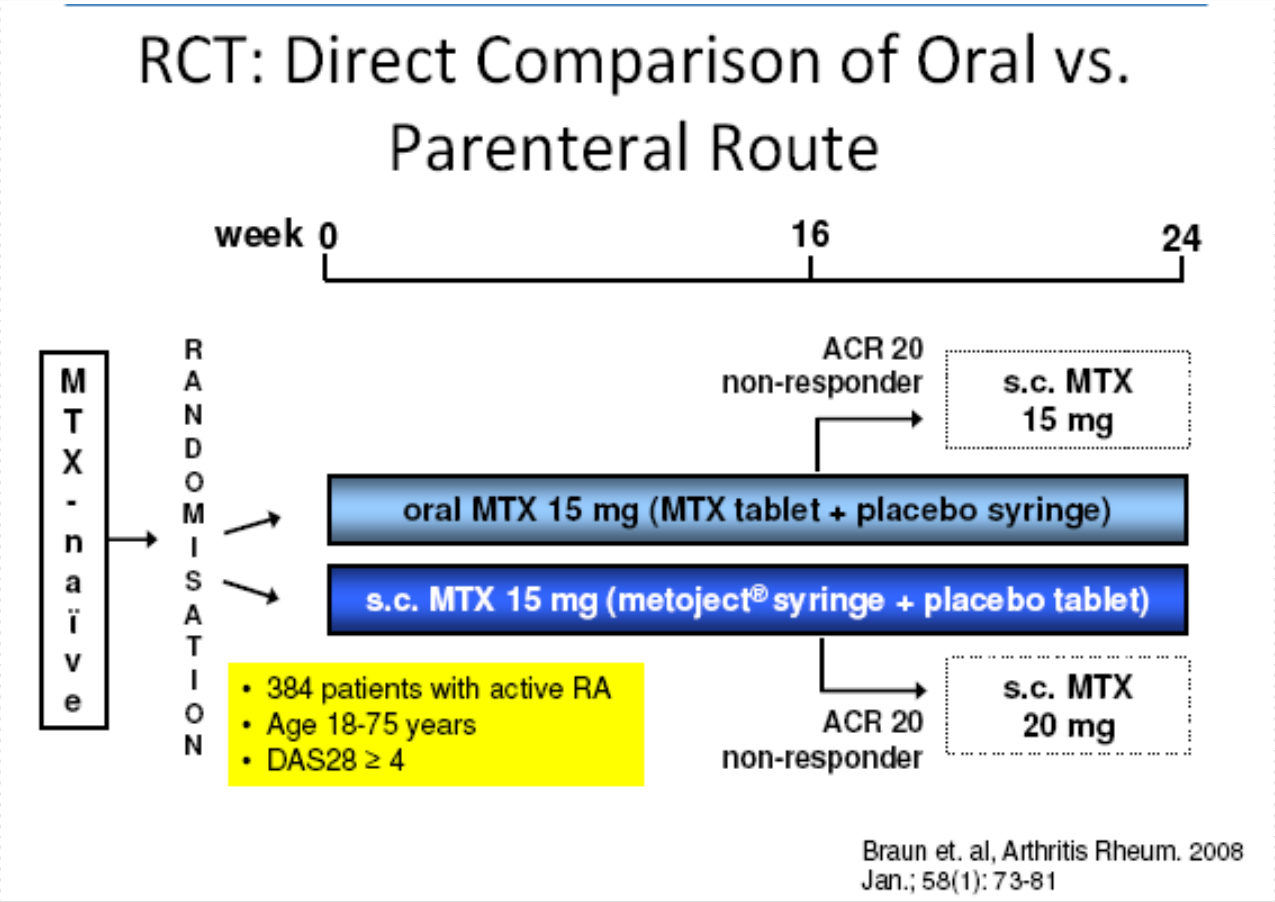
Berlin, 7 June 2012

medac satellite symposium

„ Treatment of Rheumatic Diseases:

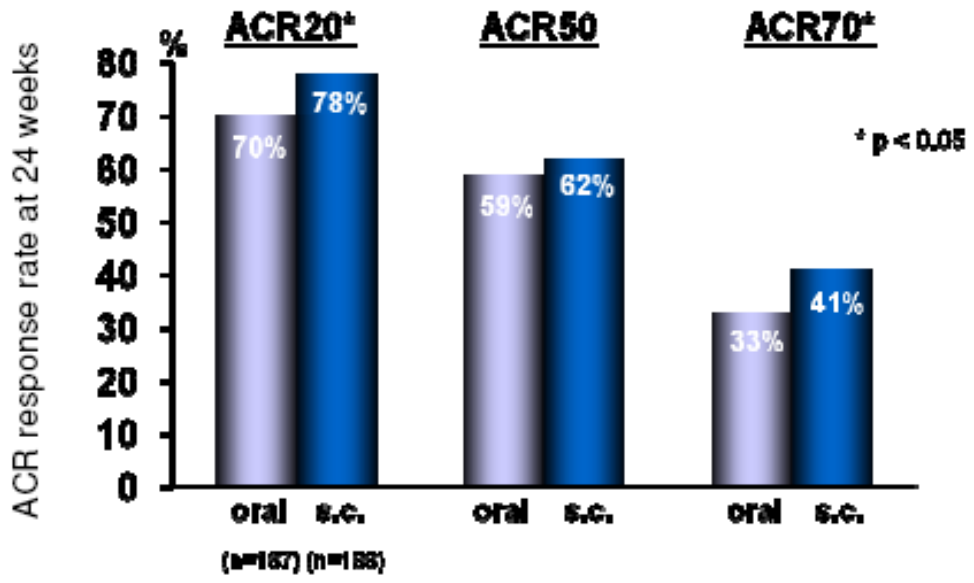
New Therapeutic Approaches & Recommendations"

Sc MTX στην PA



Sc MTX στην PA

Oral vs. Parenteral MTX: ACR Responses



Braun et. al, Arthritis Rheum. 2008 Jan.; 58(1): 73-81

Sc MTX στην PA

Effectiveness of switching low-dose MTX from oral to parenteral route

24 patients switched from

- oral MTX 17,5 mg/week (range 5-25)

to

- 15 mg (range 7,5-25 mg) parenteral

RESULTS

→ 20 patients (83%) improved

Osman A, Mulherin D, Ann Rheum Dis 2001, 60: 432

Sc MTX στην PA

Effectiveness of switching low-dose MTX from oral to parenteral route

- 103 RA patients with persistently active disease despite oral MTX
- Switched to same dose partenteral MTX because of inefficacy (n=40) or GI side effects (n=63)

	Switch for inefficacy (n = 40)	Switch for GI side effects (n = 63)
Mean DAS28 on oral MTX	**4.8**	**4.1**
Mean DAS28 after 3 months on sc MTX	**4.2** (p = 0.006)	**3.0** (p = 0.0001)
Patients in remission (DAS28 < 2.6) after 3 months on sc MTX	**4** (10%)	**15** (24%)

Hameed B et al. Intl J Rheum 2009

Sc MTX Vs per os

- Καλύτερη απόκριση στις ίδιες δόσεις
- Φιλικότερη «επαφή» με το πεπτικό
- Ίδια ανοχή
- Μείωση κόστους (καθυστέρηση …πολύ πιο ακριβών θεραπειών)

Bioavailability of low-dose MTX applied through different routes

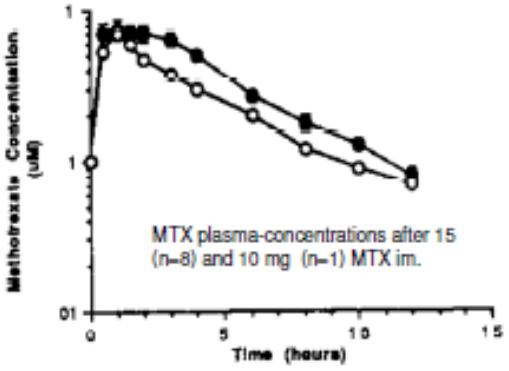
Bioavailability after oral application:

- Consistenly reported markedly **inter-individual variability** (3-30%)[2,3,4]
- **Decreasing resorption** with increasing dosis[5]

Bioavailability after sc/im application:

- **Similar to iv.-application**[6, 7, 8, 9]
- Almost **complete resorption**
- in all but one study **no substantial variability**

[1]Körber H, Med. Diss. Univ. Lübeck, 1994
[2]Lobbe C et al, Ann Rheum Dis 1994, 53: 475-7
[3]Oguey D et al, Arthritis Rheum 1992, 53: 475-7
[4]Fossa SD et al, Eur J Clin Pharmacol 1988, 34: 517-9
[5]Balis FM et al, J Clin Oncol 1988, 2: 1882-6
[6]Jundt JW et al, J Rheumatol 1993, 20: 1845-9
[7]Brooks PJ et al, Arthritis Rheum 1990, 33: 91-4
[8]Kabisch H et al, Akt Rheumatol 2004, 29: 197-200
[9]Edelman J et al, Clin Pharmacol Ther 1984, 35: 382-6



MTX plasma-concentrations after 15 (n=8) and 10 mg (n=1) MTX im.

Glynn-Barnhart AM et al, Pharacotherapy 12, 1992

Υποκλινική υμενίτιδα

[2012] [OP0275] PERSISTENCE OF ULTRASOUND SYNOVITIS IN THE PATIENTS FULLFILING THE DAS AND/OR THE NEW ACR/EULAR RA REMISSION DEFINITIONS: RESULTS OF THE SONAR SCORE APPLIED TO THE PATIENTS OF THE SCQM COHORT

P. Zufferey[1], B. Möller[2], L. Brulhart[3], G. Tamborrini[4], A. Scherer[5], H.R. Ziswiler[2], for the Rheumatologists of SCQM [1]Dal, CHUV, Lausanne; [2]Rheumatology, Inselspital, Bern;[3]Rheumatology, HUG, Geneva; [4]Rheumatology, Universitat Spital; [5]SCQM, Zurich, Switzerland

[2012] [OP0275] PERSISTENCE OF ULTRASOUND SYNOVITIS IN THE PATIENTS FULLFILING THE DAS AND/OR THE NEW ACR/EULAR RA REMISSION DEFINITIONS: RESULTS OF THE SONAR SCORE APPLIED TO THE PATIENTS OF THE SCQM COHORT

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- SONAR data
- 362 RA ασθενείς
- 121 patients πληρούσαν DAS remission (33%)
- και μόνο 29 τα νέα ACR/EULAR definition (17%)
- > 1/3 RA ασθενείς σε ύφεση είχαν ευρήματα Us-υμενίτιδας => χαμηλή ενεργότητα νόσου αλλά όχι ύφεση

PA

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Evidence for Distinct Roles of Environmental and Genetic Factors in the Emergence of Anti Citrullinated-Protein Antibodies Positive Rheumatoid Arthritis-an Epidemiological Investigation in Twins. Aase Haj Hensvold[1], Patrik KE Magnusson[2], Monika Hansson[1], Lena Israelsson[3], Cecilia Carlens[1], Johan Askling[4], Vivianne Malmström[1], Lars Klareskog[3] and Anca Irinel Catrina[1]. [1]Rheumatology unit, Karolinska University Hospital, Karolinska Institute, Stockholm, Sweden, [2]Swedish Twin Registry Karolinska Institutet, Stockholm, Sweden, [3]Karolinska Institute, Stockholm, Sweden, [4]Rheumatology Unit & Clinical Epidemiology Unit, Stockholm, Sweden

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Το περιβάλλον , ο τρόπος ζωής (life style) και «στοχαστικοί» παράγοντες (πχ κάπνισμα) είναι πιο σημαντικοί / γενετικούς στο να καθορίσουν ΠΟΙΑ ΑΤΟΜΑ ΘΑ ΑΝΑΠΤΥΞΟΥΝ ΑΣΡΑ

Οι γενετικοί παράγοντες (και κυρίως ο κοινός επίτοπος) φέρουν μεγαλύτερο «βάρος» στο να καθορίσουν ΠΟΙΑ ΑΣΡΑ-θετικά άτομα θα αναπτύξουν ΑΡΘΡΙΤΙΔΑ

Anti-TNF-α & CVD

[2012] [OP0002] USE OF ANTI-TNF THERAPY IS ASSOCIATED WITH REDUCED CARDIOVASCULAR EVENT RISK IN RHEUMATOID ARTHRITIS

M.T. Nurmohamed[1,2], Y. Bao[3], J. Signorovitch[4], P.M. Mulani[3], D.E. Furst[5] [1]VU University Medical Center; [2]Jan van Breemen Research Institute, Amsterdam, Netherlands; [3]Abbott Laboratories, Abbott Park, IL; [4]Analysis Group, Inc., Boston, MA; [5]David Geffen School of Medicine at UCLA, Los Angeles, CA, United States

Citation: Ann Rheum Dis 2012;71(Suppl3):52

Berlin
6-9 JUNE 2012

[2012] [OP0002] USE OF ANTI-TNF THERAPY IS ASSOCIATED WITH REDUCED CARDIOVASCULAR EVENT RISK IN RHEUMATOID ARTHRITIS

M.T. Nurmohamed[1,2], Y. Bao[3], J. Signorovitch[4], P.M. Mulani[3], D.E. Furst[5] [1]VU University Medical Center; [2]Jan van Breemen Research Institute, Amsterdam, Netherlands; [3]Abbott Laboratories, Abbott Park, IL; [4]Analysis Group, Inc., Boston, MA; [5]David Geffen School of Medicine at UCLA, Los Angeles, CA, United States

- Thomson Reuters MarketScan® database (2003–2010)
- 109,462 ασθενείς : 105,920 total patient-years (PYs) follow-up
  - 48,621 PYs σε anti-TNF therapies (31,466 as monotherapy)
  - 35,480 PYs σε MTX (18,325 σε monotherapy)
  - 52,994 PYs σε άλλα nonbiologic DMARDs (9,441 σε monotherapy)
- 1743 ασθενείς (1.6%) είχαν CV επεισόδιο

Citation: Ann Rheum Dis 2012;71(Suppl3):52

Berlin
6-9 JUNE 2012

[2012] [OP0002] USE OF ANTI-TNF THERAPY IS ASSOCIATED WITH REDUCED CARDIOVASCULAR EVENT RISK IN RHEUMATOID ARTHRITIS

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- Για κάθε 6 m anti-TNF σημαντική μείωση του κινδύνου
  - για CV επεισόδιο (hazard ratio [HR]=0.87, 95% confidence interval [CI]=0.80–0.96, *P*=.005)
  - Και για ΟΕΜ (HR=0.80, CI=0.67–0.95, *P*=.013), σε σχέση με ασθενείς χωρίς anti-TNF

- Η χρήση anti-TNF θεραπείας για 1, 2, ή 3 χρόνια θα μπορούσε να μειώσει τον κίνδυνο CV επεισοδίου κατά 24%, 42%, και 56%

Citation: Ann Rheum Dis 2012;71(Suppl3):52

CVD RA

ACR/ARHP 12 Scientific Meeting
Washington, D.C.
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827

Sustained Development of Cardiovascular Disease in Rheumatoid Arthritis Despite Cardioprotective Treatment: The 10-Year Prospective Carre-Study. Alper M. van Sijl[1], Inge A.M. van den Oever[1], Mike J.L. Peters[2], Vokko P. van Halm[3], Alexandre E. Voskuyl[2]. Yvo M. Smulders[2] and Mike T. Nurmohamed[1], [1]Jan van Breemen Research Institute | Reade, Amsterdam, Netherlands, [2]VU University Medical Center, Amsterdam, Netherlands, [3]Academic Medical Centre, Amsterdam, Netherlands

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- 353 RA ασθενείς μελετηθήκαν προοπτικά για 10 χρόνια
- 58 CV επεισόδια (σε 2361 patient years of follow-up)
  - incidence rate (IR) of 25.3/1.000 patient years
- Παρόμοιος κίνδυνος (IR) στα 3-years και 10-years of follow-up
  - (22.8/1.000 patient years)

Ο κίνδυνος για CVD ΠΑΡΑΜΕΝΕΙ
παρά την επιπρόσθετη αποτελεσματική αντι-φλεγμονώδη αγωγή
Και τη χρήση καρδιοπροστατευτικών αγωγών

827

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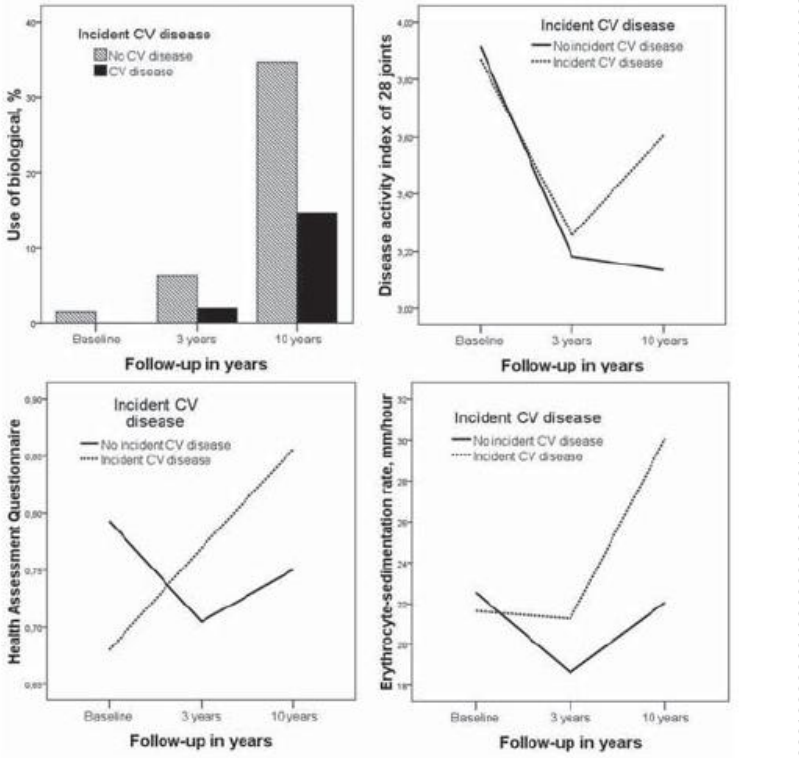
Annual Scientific Sessions: November 10-14, 2012

- αντι-υπερτασικά, στατίνες , TNF inhibitors αυξήθηκαν
- ΕΝΩ παράγοντες σχετικοί με τη RA βελτιώθηκαν σημαντικά



Figures 1–4. Changes in use of biologicals and RA factors over time stratified for incident CV disease

ACR/ARHP 12
Scientific Meeting
Washington, D.C.
Pre-Conference Courses: November 9-10, 2012
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2466

Pregnancy Outcome in Women Treated with Adalimumab for the Treatment of Rheumatoid Arthritis: The OTIS Autoimmune Diseases in Pregnancy Project.

Christina D. Chambers[1], Diana L. Johnson[1], Yunjun Luo[1], Janina L. Jimenez[1], Nicole Mirrasoul[1], Elizabeth Salas[1], Kenneth Lyons Jones[1] and OTIS Research Group[2]. [1]University of California, San Diego, La Jolla, CA, [2]La Jolla

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- 312 γυναίκες με ΡΑ
  - Έκθεση σε ADA στο 1ο 3μηνο της κύησης (69)
  - Σύγκριση με ανάλογο πληθυσμό χωρίς ADA έκθεση (80)
  - & υγιή πληθυσμό (163)
- Νοέμβριος 2004 – Μάιος 2012
- 1 έτος παρακολούθησης μετά τον τοκετό

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Αυτόματη αποβολή

- ADA : 10,1%
- Παρόμοιος πληθυσμός : 7,5%
- υγιείς : 2,5 %

- Ο σχετικός κίνδυνος (ADA vs Παρόμοιος πληθυσμός) RR : 1.33 (95% CI, 0.42, 4.28, p = 0.62)

Μη στατιστικά σημαντικό

2466

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Σοβαρές γενετικές ανωμαλίες

- ADA : 4,5 %
- Παρόμοιος πληθυσμός : 5,2 %
- υγιείς : 6,6 %

Δεν υπάρχουν σημαντικές διαφορές σε ανεπιθύμητες εκβάσεις εγκυμοσύνης μεταξύ ασθενών με ΡΑ που εκτέθηκαν σε ADA και αυτών χωρίς

Ούτε κάποιου ειδικού τύπου ανωμαλία

NSAIDs : DMARDs στην AS?

[2012] [OP0247] REDUCTION OF RADIOGRAPHIC SPINAL PROGRESSION IN PATIENTS WITH ANKYLOSING SPONDYLITIS TREATED WITH NON-STEROIDAL ANTI-INFLAMMATORY DRUGS IS MOST EVIDENT IN THE PRESENCE OF SYNDESMOPHYTES AND ACTIVE SYSTEMIC INFLAMMATION

D. Poddubnyy[1], H. Haibel[1], J. Listing[2], E. Märker-Hermann[3], H. Zeidler[4], J. Braun[5], M. Rudwaleit[6], J. Sieper[1] [1]Charité Universitätsmedizin Berlin; [2]German Rheumatism Research Centre, Berlin; [3]Dr. Horst Schmidt Kliniken, Wiesbaden; [4]Medizinische Hochschule, Hannover; [5]Rheumazentrum Ruhrgebiet, Herne; [6]Endokrinologikum, Berlin, Germany

Berlin

[2012] [OP0247] REDUCTION OF RADIOGRAPHIC SPINAL PROGRESSION IN PATIENTS WITH ANKYLOSING SPONDYLITIS TREATED WITH NON-STEROIDAL ANTI-INFLAMMATORY DRUGS IS MOST EVIDENT IN THE PRESENCE OF SYNDESMOPHYTES AND ACTIVE SYSTEMIC INFLAMMATION

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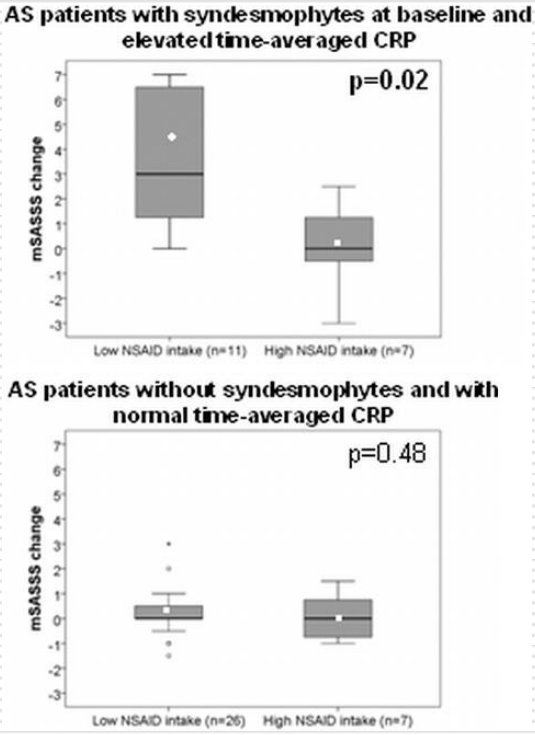
- AS ασθενείς με **υψηλή λήψη ΜΣΑΦ** είχαν μικρότερη ακτινολογική εξέλιξη ΣΣ (mSASSS score σε 2 χρόνια) σε σχέση με ασθενείς με χαμηλή λήψη
  - 0.02±1.38 vs. 0.96±2.78 mSASSS units

- Τα ευρήματα ήταν εντυπωσιακά κυρίως σε ασθενείς με υψηλό κίνδυνο για α-α εξέλιξη
  - Συνδεσμόφυτα
  - CRP



EULAR ΣΕΛ

[2012] [OP0064] JOINT EULAR/ERA-EDTA RECOMMENDATIONS FOR THE MANAGEMENT OF ADULT AND PEDIATRIC LUPUS NEPHRITIS

G. Bertsias[1], M. Tektonidou[2], Z. Amoura[3], M. Aringer[4], I. Bajema[5], J. Berden[6], J. Boletis[7], R. Cervera[8], T. Dörner[9], A. Doria[10], F. Ferrario[11], J. Flöge[12], F. Houssiau[13], J.P. Ioannidis[14], D. Isenberg[15], C.G. Kallenberg[16], L. Lightstone[17], S. Marks[18], A. Martini[19], G. Moroni[20], I. Neumann[21], P. Niaudet[22], M. Praga[23], M. Schneider[24], V. Tesar[25], C. Vasconcelos[26], R. van Vollenhoven[27], E. Zakharova[28], M. Haubitz[29], C. Gordon[30], D. Jayne[31], D. Boumpas[1] [1]University of Crete, Heraklion; [2]Rheumatology, University of Athens, Athens, Greece; [3]Hôpital Pitié-Salpêtrière, Paris, France; [4]Universitätsklinikum Carl Gustav Carus, Dresden, Germany; [5]Leiden University Medical Center, Leiden; [6]Ncmls, Nijmegen, Netherlands; [7]Laiko Hospital, Athens, Greece; [8]Universitat de Barcelona, Barcelona, Spain; [9]Charité - Universitätsmedizin Berlin, Berlin, Germany; [10]University of Padova, Padova; [11]San Carlo Borromeo Hospital and Fondazione, Milan, Italy; [12]University Hospital, Aachen, Germany; [13]Université catholique de Louvain, Brussels, Belgium; [14]Stanford University School of Medicine, Stanford, United States; [15]University College Hospital, London, United Kingdom; [16]University Hospital Groningen, Groningen, Netherlands; [17]Imperial College London; [18]University College London Institute of Child Health, London, United Kingdom; [19]University of Genoa, Genoa; [20]Fondazione Ospedale Maggiore Policlinco, Milan, Italy; [21]Fachärztin für Innere Medizin, Wien, Austria; [22]Hopital Necker Enfants Malades Tour Lavoisier, Paris, France; [23]Hospital 12 de Octubre, Madrid, Spain; [24]Heinrich-Heine-University Duesseldorf, Duesseldorf, Germany; [25]Charles University, Praque, Czech Republic; [26]Centro Hospitalar do Porto, Porto, Portugal; [27]Karolinska Institute, Stockholm, Sweden; [28]University of Moscow, Moscow, Russian Federation; [29]Medizinische Hochschule, Hannover, Germany; [30]University of Birmingham; [31]Cambridge University, London, United Kingdom

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- Κανένα κλινικό , ορολογικό, εργαστηριακή εξέταση δεν είναι σε θέση να προβλέψει τα ευρήματα της βιοψίας
- Κάθε εύρημα νεφρικής προσβολής (κυρίως πρωτεϊνουρία > >0.5 g/24-hr) χρήζει βιοψίας
- Για τους περισσότερους ασθενείς τάξης ISN/RPS2003 Class IIIA ή A/C and Class IVA or A/C (±V) LN, συνιστάται
  - mycophenolate mofetil (MMF) ή
  - χαμηλές δόσεις IV cyclophosphamide (CY)

σε συνδυασμό με γλυκοκορτικοειδή

- Συν-χορήγηση αρχικά 3 ημερήσιες ώσεις IV methylprednisolone, και στη συνέχεια : oral prednisolone 0.5 mg/kg/day

G. Bertsias[1], M. Tektonidou[2], Z. Amoura[3], M. Aringer[4], I. Bajema[5], J. Berden[6], J. Boletis[7], R. Cervera[8], T. Dörner[9], A. Doria[10], F. Ferrario[11], J. Flöge[12], F. Houssiau[13], J.P.

- Για αμιγή class V νόσο με νεφρωτικού τύπου πρωτεϊνουρία
  - MMF σε συνδυασμό με oral prednisolone μπορεί αρχικά να χορηγηθεί
- Για την διατήρηση της ανοσοκαταστολής συνιστάται MMF ή azathioprine για τουλάχιστον 3 χρόνια
- Για αποτυχία σε MMF ή CYC => αλλαγή στο άλλο ή rituximab

EULAR, στεροειδή

[2012] [OP0006] EULAR EVIDENCE BASED RECOMMENDATIONS ON THE MANAGEMENT OF MEDIUM TO HIGH DOSE SYSTEMIC GLUCOCORTICOID THERAPY IN RHEUMATIC DISEASES

N. Duru[1], M.C. van der Goes[1], J.W. Jacobs[1], T. Andrews[2], M. Boers[3], F. Buttgereit[4], N. Caeyers[5], M. Cutolo[6], S. Halliday[2], J.A. da Silva[7], J.R. Kirwan[8], D. Ray[9], J. Rovensky[10], G. Severijns[5], R. Westhovens[11], J.W. Bijlsma[1] [1]Rheumatology & Clinical Immunology, University Medical Center Utrecht, Utrecht, Netherlands; [2]EULAR Social Leagues, Patients' Representative, Bristol, United Kingdom; [3]Clinical Epidemiology and Biostatistics, VU University Medical Centre, Amsterdam, Netherlands; [4]Rheumatology and Clinical Immunology, Charité Universitätsmedizin Berlin, Berlin, Germany; [5]EULAR Social Leagues, Patients' Representative, Leuven, Belgium; [6]Research Laboratory and Division of Rheumatology, Department of Internal Medicine, University of Genova, Genova, Italy; [7]Reumatologia, Hospitais da Universidade de Coimbra, Coimbra, Portugal; [8]University of Bristol Academic Rheumatology Unit, Bristol Royal Infirmary, Bristol; [9]Department of Endocrinology & Diabetes Group, Developmental Biomedicine Research Group, University of Manchester, Manchester, United Kingdom; [10]National institute of Rheumatic Diseases, Piest'any, Slovakia; [11]Rheumatology, University Hospitals KU Leuven, Leuven, Belgium

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- Ενημέρωση ασθενούς – περιβάλλοντος- οικογενειακού ιατρού
- Δίαιτα – άσκηση – πληγές
- Εκτίμηση κινδύνου οστεοπόρωσης – παρέμβαση
- Καταστολή άξονα

[2012] [OP0006] EULAR EVIDENCE BASED RECOMMENDATIONS ON THE MANAGEMENT OF MEDIUM TO HIGH DOSE SYSTEMIC GLUCOCORTICOID THERAPY IN RHEUMATIC DISEASES

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Συνοσηρότητα υψηλών δόσεων

- Διαβήτης
- CVD
- Πεπτικό έλκος
- Λοιμώξεις
- Ανοσοκαταστολή
- Γλαύκωμα
- Οστεοπόρωση

[2012] [OP0006] EULAR EVIDENCE BASED RECOMMENDATIONS ON THE MANAGEMENT OF MEDIUM TO HIGH DOSE SYSTEMIC GLUCOCORTICOID THERAPY IN RHEUMATIC DISEASES

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Παρακολούθηση

- ΣΔ, ΑΥ, δυσλιπιδαιμία
- ΣΒ
- Οίδημα ΚΑ
- Οστεοπόρωση
- Λοιμώξεις
- Οστεονέκρωση
- Μυοπάθεια
- Προβλήματα όρασης
- Δέρμα
- Νευρο-ψυχολογικές διαταραχές

Κορτιζόνη στην ΟΑ ?

[2012] [OP0129] EFFECT OF LOW DOSE ORAL PREDNISOLONE ON SYMPTOMS AND SYSTEMIC INFLAMMATION IN OLDER ADULTS WITH MODERATE TO SEVERE KNEE OSTEOARTHRITIS: A RANDOMIZED PLACEBO-CONTROLLED TRIAL

A. Abou-Raya[1], S. Abou-Raya[1], M. Helmii[2], T. Khadrawi[3] [1]Rheumatology, Faculty of Medicine, University of Alexandria & Alexandria Centre for Women's Health; [2]Biochemistry, Medical Research Institute; [3]Orthopaedics, Faculty of Medicine, University of Alexandria, Alexandria, Egypt

Berlin 6-9 JUNE 2012

[2012] [OP0129] EFFECT OF LOW DOSE ORAL PREDNISOLONE ON SYMPTOMS AND SYSTEMIC INFLAMMATION IN OLDER ADULTS WITH MODERATE TO SEVERE KNEE OSTEOARTHRITIS: A RANDOMIZED PLACEBO-CONTROLLED TRIAL

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- 125 ασθενείς
- 63 ασθενείς :7.5 mg/day prednisolone και 62: placebo (6w)

- Στατιστικά σημαντική **μείωση του πόνου** στο γόνατο στην ομάδα παρέμβασης ($p<0.001$)
  - Τα αποτελέσματα παρέμειναν μέχρι την 12 εβδομάδα
- Σημαντική βελτίωση στην φυσική λειτουργικότητα
- Μείωση επιπέδων IL-1, IL-6, TNF-alpha και hsCRP
- Μείωση χρήση ΜΣΑΦ
- Δεν αναφέρθηκαν σοβαρές ανεπιθύμητες δράσεις

αντι-οστεοπορωτικά φάρμακα στην ΟΑ ?

Washington, D.C. ACR/ARHP 12 Scientific Meeting
Pre-Conference Courses: November 9-10, 2012
Annual Scientific Sessions: November 10-14, 2012

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Effects of Strontium Ranelate On Knee Osteoarthritis Pain: A Responder Analysis. JY. Reginster[1], Roland Chapurlat[2], N. Bellamy[3], E. Czerwinski[4], JP Devogelaer[5], L. March[6], K. Pavelka[7] and Cyrus Cooper[8]. [1]University of Liège, Liège, Belgium, [2]Hôpital Edouard Herriot, Lyon, France, [3]CONROD. The University of Queensland, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia, [4]Krakow Medical Centre, Kraków, Poland, [5]Cliniques Universitaires St. Luc, Brussels, Belgium, [6]University of Sydney, Insitute of Bone and Joint Research, Royal North Shore Hospital, St Leonards - Sydney, Australia, [7]Institute of Rheumatology, Prague 2, Czech Republic, [8]University of Oxford; Southampton General Hospital, Southampton, United Kingdom

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Clinically Meaningful Effect of Strontium Ranelate On Knee Osteoarthritis Symptoms. O. Bruyere[1], N. Bellamy[2], J. Brown[3], P. Richette[4], L. Punzi[5], X. Chevalier[6], Cyrus Cooper[7] and Jean-Yves Reginster[1]. [1]University of Liège, Liège, Belgium, [2]CONROD. The University of Queensland, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia, [3]Rheumatology Centre, Quebec City, QC, [4]Hôpital Lariboisière, Paris, France, [5]Azienda Ospedaliera di Padova, Padova, Italy, [6]Hôpital Henri-Mondor, Creteil, France, [7]University of Oxford; Southampton General Hospital, Southampton, United Kingdom

αντι-οστεοπορωτικά φάρμακα στην ΟΑ ?

- SEKOIA RCT μελέτη
- 3 χρόνια, 1371 ασθενείς (ITT) με ΟΑ γονάτου
- strontium ranelate 2g/day
- 20% βελτίωση στο WOMAC pain vs placebo (72% vs 64%)
  - & φυσική λειτουργικότητα

SS RTX ΕΟΦ

Β. ΣΥΣΤΗΜΑΤΙΚΕΣ ΕΚΔΗΛΩΣΕΙΣ

- **ΚΟΠΩΣΗ**

-Τρικυκλικά αντικαταθλιπτικά

- **ΑΡΘΡΑΛΓΙΕΣ/ΑΡΘΡΙΤΙΔΑ**

1ης επιλογής

-Υδροξυχλωροκίνη(200mg/ημέρα)

ή

-Πρεδνιζολόνη ≤7,5mg/ημέρα

+

-Μεθοτρεξάτη(7.5-15mg/ημέρα)

2ης επιλογής

rituximab IV 1000mg x 2 σε μεσοδιάστημα 15 ημερών κάθε 6 ή 8 'ή 10 μήνες ανάλογα με την κλινική εκτίμηση

- **ΣΥΣΤΗΜΑΤΙΚΗ ΑΓΓΕΙΙΤΙΔΑ**

-κορτικοστεροειδή(0.5-1mg/kg βάρους)

-rituximab IV 1000mgx2 σε μεσοδιάστημα 15 ημερών άπαξ.

Το σχήμα μπορεί να επαναληφθεί μετά από 6 μήνες ή αργότερα μόνον εφ' όσον υπάρχουν κλινικές ενδείξεις

RTX σε SS

[2012] [OP0066] EFFICACY OF RITUXIMAB IN SYSTEMIC MANIFESTATIONS OF PATIENTS WITH PRIMARY SJÖGREN'S SYNDROME: RESULTS FROM THE AIR REGISTRY

G. Cinquetti[1], C. Larroche[2], B. Combe[3], E. Hachulla[4], O. Meyer[5], E. Pertuiset[6], G. Kaplanski[7], X. Mariette[8], J.-E. Gottenberg[9], and Club Rhumatismes et Inflammations [1]HIA Legouest, Metz; [2]CHU Avicenne, Bobigny; [3]CHU Montpellier, Montpellier; [4]CHU Lille, Lille; [5]Hôpital Bichat, Paris; [6]CH Pontoise, Pontoise; [7]Hôpital de la Conception, Marseille; [8]Hôpital Bicêtre, Paris; [9]CHU Hautepierre, Strasbourg, France

[2012] [OP0066] EFFICACY OF RITUXIMAB IN SYSTEMIC MANIFESTATIONS OF PATIENTS WITH PRIMARY SJÖGREN'S SYNDROME: RESULTS FROM THE AIR REGISTRY

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- AutoImmune and Rituximab registry (AIR) : προοπτική παρακολούθηση 5 y
- 86 ασθενείς με pSS υπο RTX
- Προσβολή : αρθρώσεις, νευρικό σύστημα , πνεύμονα, νεφρό, αιματολογική, αγγειίτιδα
- Αποτελεσματικότητα : 47 pts (60%) μετά τον 1st κύκλο RTX
- Ασφάλεια :
  - 4 σοβαρές άμεσες αντιδράσεις στην έγχυση
  - 1 επεισόδιο ορονοσίας
  - 41 ασθενείς διέκοψαν

RTX σε SS

Washington, D.C. ACR/ARHP 12 Scientific Meeting
Pre-Conference Courses: November 9-10, 2012
Annual Scientific Sessions: November 10-14, 2012

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Tolerance and Efficacy of Rituximab in Primary Sjogren Syndrome: Final Results of a Randomized Controlled Trial.

Valerie Devauchelle-Pensec[1], Xavier Mariette[2], Sandrine Jousse-Joulin[3], Jean-Marie Berthelot[4], Aleth Perdriger[5], Eric Hachulla[6], Xavier Puechal[7], Véronique Le Guern[8], Jean Sibilia[9], Jacques-Eric Gottenberg[10], Laurent Chiche Sr.[11], Vincent Goeb[12], Gilles Hayem[13], Jacques Morel[14], Charles Zarnitsky[15], JJ Dubost[16], Jacques-Olivier Pers[17], Emmanuel Nowak[18] and Alain Saraux[19]. [1]Brest Occidentale university, Brest, France, [2]Université Paris-Sud, Le Kremlin Bicetre, France, [3]Brest university medical school, EA 2216, UBO and CHU de la Cavale Blanche, Brest, France, [4]Nantes University Hospital, Nantes, France, [5]Hôpital Sud, Rennes, France, [6]Department of Internal Medicine, Claude Huriez Hospital, University of Lille, Lille CEDEX, France, [7]Hôpital Cochin, Paris, France, [8]Cochin Hospital, Paris, France, [9]EA4438 Laboratoire Physiopathologie des Arthrites, Illkirch-Strasbourg, France, [10]Strasbourg University Hospital, Strasbourg, France, [11]Internal Medicine, CHU Marseille, Marseille, France, [12]Rouen University Hospital, Rouen, France, [13]Bichat Hospital, Paris, France, [14]Hopital Lapeyronie, Montpellier, France, [15]CH du Havre, Le Havre, France, [16]CHU CLERMONT-FERRAND, Clermont-Ferrand, France, [17]Brest Occidentale University, Brest, France, [18]CHU Brest, Brest, France, [19]Université Brest Occidentale, Brest, France

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Washington, D.C. ACR/ARHP 12 Scientific Meeting
Pre-Conference Courses: November 9-10, 2012
Annual Scientific Sessions: November 10-14, 2012

- Πολυκεντρική, διπλά τυφλή, ελεγχόμενη με placebo – 24 w
- 122 ασθενείς
- 11/53 (20.7%) υπο placebo και 13/60 (21.7%) υπο RTX είχαν **επιθυμητή απόκριση** (P = 0.9)
- Παρόμοια αποτελέσματα και για 30 ακόμη σημεία (υμενίτιδα)
  - Εκτός από sicca & κόπωση (P< 0.05)
- ESDAI score (συστηματικές εκδηλώσεις)

APS

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Efficacy of Aspirin for the Prevention of the First Thrombo-Embolic Events in Patients with Antiphospholipid Antibodies: A Meta-nalysis of Literature Data. Laurent Arnaud[1], Alexis Mathian[1], Amelia Ruffatti[2], Maria Tecktonidou[3], Ricard Cervera[4], Ricardo Forastiero[5], Vittorio Pengo[6], Marc Lambert[7], Stephane Zuily[8], Denis Wahl[8] and Zahir Amoura[1]. [1]Hôpital Pitié-Salpêtrière, AP-HP, UPMC Univ Paris 06 & French National Reference Center For Systemic Lupus and Anti-phospholipid Syndrome, Paris, France, [2]Rheumatology Unit, Depart-ment of Clinical and Experimental Medicine, University of Padua, Padua, Italy, [3]First Department of Internal Medicine, School of Medicine, National University of Athens, Athens, Greece, [4]Hospital Clínic of Barcelona, Barcelona, Spain, [5]Favaloro University, Argentina, [6]Clinical Cardiology, Department of Cardiac Thoracic and Vascular Sciences, University of Padova, Padova, Italy, [7]Internal Medicine Department, Universitary hospital, Lille, France, [8]Nancy University Hospital, Université de Lorraine & INSERM U961, Vandoeuvre-Les-Nancy, France

2459

Efficacy of Aspirin for the Prevention of the First Thrombo-Embolic Events in Patients with Antiphospholipid Antibodies: A Meta-nalysis of Literature Data. Laurent Arnaud[1], Alexis Mathian[1], Amelia

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- μετα-ανάλυση 9 μελετών (8 παρατήρησης και 1 παρέμβασης)
- 1136 ασθενείς με aPL αντισώματα – 133 συμβάματα

- ο συνολικός κίνδυνος (*the overall pooled odds ratio for the risk*) για το 1ο θρομβωτικό επεισόδιο σε ασθενείς υπο ASA: 0.48 (95%CI: 0.24 - 0.93)

- Ο προστατευτικός ρόλος αφορούσε μόνο :
  - αρτηριακή και όχι φλεβική θρόμβωση
  - αναδρομικές μελέτες

Scl

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728

Does the Use of Angiotensin Converting Enzyme Inhibitors Prior to Scleroderma Renal Crisis Affect Prognosis ? – Results of the International Scleroderma Renal Crisis Survey. Marie Hudson[1], Murray Baron[2], Solene Tatibouet[1], De Furst[3], Dinesh Khanna[4] and International Scleroderma Renal Crisis Study Investigaots[5]. [1]McGill University, Montreal, QC, [2]Jewish General Hospital, Montreal, QC, [3]University of California at Los Angeles, Los Angeles, CA, [4]University of Michigan, Ann Arbor, MI, [5]Montreal

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- Προοπτική μελέτη παρατήρησης (589 ιατροί σε όλο τον κόσμο)
- 88 επεισόδια νεφρικής κρίσης
  - 18 Ασθενείς (24%) ΜΟΛΙΣ είχαν ξεκινήσει ACE inhibitor
- Στον 1ο χρόνο, συνολικά:
  - 36% είχαν πεθάνει
  - 17% σε αιμοδιάλυση

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- Ο κίνδυνος για θάνατο (ACE) : 1.56 (95% confidence interval [CI] 0.70–3.47)

(*crude one-year cumulative incidence of death*)

- *The crude Cox proportional hazard ratio comparing the time to death of SRC patients exposed to ACE inhibitors prior to the onset of SRC to those unexposed was 1.95 (95% CI 0.87–4.35)*

- *After controlling for differences in prednison exposure and history of systemic hypertension in the two groups, the adjusted Cox proportional hazard ratio comparing the time to death of* ***SRC patients exposed to ACE inhibitors prior to the onset of SRC to those unexposed was 2.52*** *(95% CI 1.05–6.05, p_0.0394)*

Η έκθεση σε α-ACE πριν τη νεφρική κρίση σχετίζεται με
ΑΥΞΗΜΕΝΟ ΚΙΝΔΥΝΟ ΘΑΝΑΤΟΥ
κατά τον 1ο χρόνο μετά από SRC

Μια ματιά στο…μέλλον (PA)

2487

24-Week Results of a Blinded Phase 2b Dose-Ranging Study of Baricitinib, an Oral Janus Kinase 1/Januse Kinase 2 Inhibitor, in Combination with Traditional Disease Modifying Antirheumatic Drugs in Patients with Rheumatoid Arthritis. Mark C. Genovese[1], Edward Keystone[2], Peter Taylor[3], Edit Drescher[4], Pierre-Yves Berclaz[5], Chin H. Lee[5], Douglas E. Schlichting[5], Scott D. Beattie[5], Rosanne K. Fidelus-Gort[6], Monica E. Luchi[6] and William Macias[5]. [1]Stanford University Medical Center, Palo Alto, CA, [2]University of Toronto, Toronto, ON, [3]University of Oxford, Oxford, United Kingdom, [4]Veszprém Csolnoky Ferenc County Hospital, Department of Rheumatology and Physical Rehabilitation, Veszprém, Hungary, [5]Eli Lilly and Company, Indianapolis, IN, [6]Incyte Corporation, Wilmington, DE

2487

24-Week Results of a Blinded Phase 2b Dose-Ranging Study of Baricitinib, an Oral Janus Kinase 1/Januse Kinase 2 Inhibitor, in Combination with Traditional Disease Modifying Antirheumatic Drugs in Patients with Rheumatoid Arthritis.

Mark C. Genovese[1], Edward Keystone[2], Peter

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- 301 ασθενείς
- baricitinib doses (1, 2, 4, ή 8 mg)

Table 1. Primary and Selected Secondary Efficacy Endpoints at 12-and 24 weeks

	PBO (N=98)	1 mg QD (N=49)	2mg QD (N=52)	4 mg QD (N=52)	8 mg QD (N=50)
12 weeks					
% ACR20†	41	57*	54	75*	78*
% ACR50†	10	31*	17	35*	40*
% ACR70†	2	12*	8	23*	20*
% DAS28CRP<2.6†	4	14*	15*	37*	22*
%CDAI ≤2.8†	1	2	6	21*	12*
DAS28-CRP§	4.5	4.0*	4.0*	3.2*	3.6*
CDAI§	23.7	20.8	20.7	13.7*	16.3*
HAQ-DI Δ from baseline§	−0.10	−0.35*	−0.18	−0.33*	−0.39*
24 weeks					
% ACR20†	—	—	63	78	73
% ACR50†	—	—	20	48	55
% ACR70†	—	—	10	28	24
% DAS28CRP<2.6†	—	—	16	34	37
%CDAI ≤2.8†	—	—	8	23	22
DAS28-CRP	—	—	3.9	3.0	3.3
CDAI	—	—	19.4	11.1	12.9
HAQ-DI Δ from baseline	—	—	−0.19	−0.33	−0.45

Mean (SD)	2 mg QD	4 mg QD	8 mg QD
Hemoglobin (g/dL)	−0.28 (1.1)	−0.24 (0.9)	−0.44 (1.0)
Neutrophil count (10^3/mm^3)	−0.25 (2.2)	−0.21 (2.0)	−1.37 (2.3)
Creatinine (mg/dL)	0.04 (0.10)	0.05 (0.08)	0.07 (0.13)
HDL cholesterol (mg/dL)	5.63 (12.21)	5.40 (10.62)	8.24 (13.05)
LDL cholesterol (mg/dL)	11.52 (22.80)	8.75 (32.60)	13.98 (30.87)

Μια ματιά στο...μέλλον (PA)

1331

Once Daily High Dose Regimens of GLPG0634 in Healthy Volunteers Are Safe and Provide Continuous Inhibition of JAK1 but Not JAK2.

Florence Namour[1], René Galien[1], Lien Gheyle[2], Frédéric Vanhoutte[3], Béatrice Vayssière[1], Annegret Van der Aa[3], Bart Smets[3] and Gerben van 't Klooster[3]. [1]Galapagos SASU, Romainville, France, [2]SGS Clinical Pharmacology Unit, Antwerp, Belgium, [3]Galapagos NV, Mechelen, Belgium

Μια ματιά στο…μέλλον (οστεοπόρωση)

727

Effects of Odanacatib On BMD and Overall Safety in the Treatment of Osteoporosis in Postmenopausal Women Previously Treated with Alendronate. Roland Chapurlat[1], Sydney Bonnick[2], Tobias De Villiers[3], Alberto Odio[4], Santiago Palacios[5], Boyd Scott[6], Celine Le Bailly De Tilleghem[7], Carolyn DaSilva[6], Albert Leung[8] and Deborah Gurner[8]. [1]Hôpital Edouard Herriot, Lyon, France, [2]Cooper Clinic, Dallas, TX, [3]Mediclinic Panorama, Cape Town, South Africa, [4]Alta California Medical Group, Simi Valley, CA, [5]Instituto Palacios, Madrid, Spain, [6]Merck Sharp & Dohme Corp., Whitehouse Station, NJ, [7]Merck Sharp & Dohme Corp., Brussels, Belgium, [8]Whitehouse Station, NJ

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- Από του στόματος αναστολέας cathepsin K για μετα-εμμηνοπαυσιακή ΟΠ
- RCT : 50 mg/εβδ Vs placebo
  - BMD & βιοχημικές δείκτες σε ασθενείς με Ηχ αλεδρονάτης
- 24 μήνες

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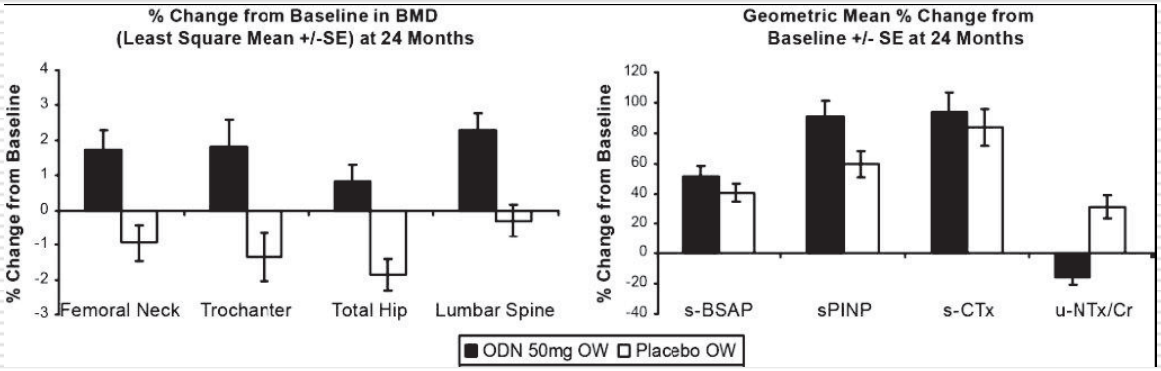

- Αλλαγές στην BMD 1.73% (αυχένα), 1.83% (τροχ) , 0.83% (ισχίο) 2.28% (οσφύ)
- Μείωση δεικτών οστικής απορρόφησης & αύξηση δεικτών οστικού σχηματισμού
- Παρόμοιες ΑΕ

- Head to head μελέτες
- Ανατροπές :
  - NSAIDs στην AS: DMARDs ?
  - MTX στην ΨΑ ?
  - αMEA στο SCL ?
  - Θεραπεία ΟΑ με αντι-οστεοπορωτική αγωγή ?
- EULAR «συστάσεις»
- Νέες θεραπευτικές επιλογές (κινάσεις, οστεοπόρωση, IL12/23)
- Αναπάντητα ερωτήματα (RTX στο SS, CVD στη PA)


ευχαριστώ ειλικρινά
για την προσοχή σας