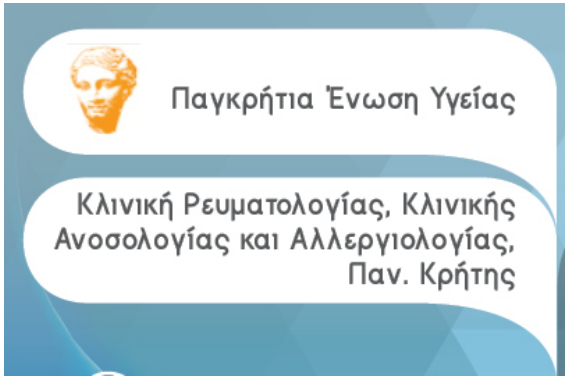
Παγκρήτια Ένωση Υγείας

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

« Σπονδυλαρθρίτιδες, ουρική αρθρίτιδα, οστεοπόρωση, ρευματική πολυμυαλγία/γιγαντοκυτταρική αρτηριίτιδα»

Ι. ΠΑΠΑΛΟΠΟΥΛΟΣ

EULAR 2015



Παγκρήτια Ένωση Υγείας

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

Abstract session

Axial SpA: Clinical

Παγκρήτια Ένωση Υγείας

PATIENTS WITH FIBROMYALGIA (FM) DO NOT FULFILL CLASSIFICATION CRITERIA FOR AXIAL SPONDYLOARTHRITIS (AXSPA) BUT PATIENTS WITH AXSPA MAY FULFILL CLASSIFICATION CRITERIA FOR FM

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X.Baraliakos et al

- **Question:** Similarities and differences between axSpA and FM using different sets of classification criteria and to assess the severity of wide-spread pain in both diseases

- **Methods:** Prospective study that included pts diagnosed as:

- Axial SpA
- FM
- RA (inflammatory control group)
- Pts on anti-TNF treatment were not included.

Παγκρήτια Ένωση Υγείας

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Results:

- Expectedly, the gender ratio differed: FM and RA patients were mostly **female (93.4% and 76.7%,** respectively), as compared to axSpA patients (**28.3%).**
- The ASAS classification criteria **were not fulfilled** by any FM pt.
- In contrast, the 1990 and 2010 FM criteria were fulfilled by 98.3% and 100% of patients with FM, but also by **14.3%** and **34.1**% of axSpA (no differences between AS and nr-axSpA) and **30%** and **46.7%** of RA patients, respectively.
- FM patients reported the highest pain scores on a 0-10 numeric rating scale
- Mean CRP values were higher in axSpA (1.1±1.3) and RA (0.6±0.9) patients vs. FM (0.4±0.4) (both $p<0.001$)

Παγκρήτια Ένωση Υγείας

PATIENTS WITH FIBROMYALGIA (FM) DO NOT FULFILL CLASSIFICATION CRITERIA FOR AXIAL SPONDYLOARTHRITIS (AXSPA) BUT PATIENTS WITH AXSPA MAY FULFILL CLASSIFICATION CRITERIA FOR FM

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Conclusions:

- No FM patients fulfilled ASAS classification criteria.
- Only a small proportion of patients with axSpA fulfilled any of the FM classification criteria.
- Less overlap between patients with FM, axSpA and RA using the 1990 criteria as compared to the more sophisticated 2010 FM criteria.
- FM patients reported higher pain scores and more functional deficits.
- Some patients with widespread pain may have underlying axSpA - this differential diagnosis needs to be taken into account when dealing with the diagnosis of FM in daily practice.

Abstract session

Axial SpA: Disease modification

Παγκρήτια Ένωση Υγείας

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

THE EFFECT OF TNF INHIBITION ON RADIOGRAPHIC PROGRESSION IN ANKYLOSING SPONDYLITIS: AN OBSERVATIONAL COHORT STUDY OF 384 PATIENTS

W.P. Maksymowych et al (Canada)

- **Question**: Impact of anti-TNF therapy on radiographic progression in AS

- **Methods:**

- Observational cohort(FORCAST), 384 pts
- Mean follow up of 3.3 years for clinical and laboratory outcomes every 6 months
- Standard therapy (n=**148**) **VS** anti-TNF (n=**236**)

Παγκρήτια Ένωση Υγείας

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Results:

Significant predictors of progression:

- ***Baseline mSASSS (p<0.001)***
- ***ASDAS (p=0.025),***
- ***Male sex (p=0.026)***
- ***Age (p=0.001), and***
- ***Disease duration (p=0,003)***
- ***CRP at post-treatment of <6mg/ L (p=0.024).***

Non significant predictors:

- ***Smoking,***
- ***HLA- B27***
- ***NSAIDs***
- ***Anti-TNF therapy (yes/no)***
- ***Duration of anti-TNF therapy***
- ***Proportion of disease duration exposed to anti-TNF***

➢**Significantly less radiographic progression in patients who received anti-TNF within 5 years of disease onset (n=15) when compared to those receiving treatment after *>10 years of disease (n=178) or on standard therapy (p=0.01 for* both).**

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➢ Conclusions:

- Anti-TNF therapy demonstrated ***no effect on radiographic progression*** in this observational cohort.
- ***Early treatment*** may be a factor in reducing progression although only a small proportion of patients receive early intervention with anti-TNF in routine practice.

Παγκρήτια Ένωση Υγείας

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

CONTINUOUS VERSUS ON DEMAND TREATMENT OF ANKYLOSING SPONDYLITIS WITH DICLOFENAC OVER 2 YEARS DOES NOT PREVENT RADIOGRAPHIC PROGRESSION OF THE SPINE – RESULTS FROM A RANDOMIZED PROSPECTIVE MULTI-CENTER TRIAL (ENRADAS)

J. Sieper et al (Germany)

- **Question:** To assess whether NSAIDs given continuously reduce radiographic progression compared to an on demand therapy in patients with AS.

- **Methods:**
- Prospective randomized trial.
- Patients were randomized to be treated with either continuous (at least 50% per day of the maximum dose of 150 mg) or on demand diclofenac for 2 years.
- Switching to another NSAID was possible in case of side effects or inefficacy
- TNF-blockers were not allowed
- **Primary endpoint**: **Difference in radiographic spinal progression** measured by the mSASSS

Παγκρήτια Ένωση Υγείας

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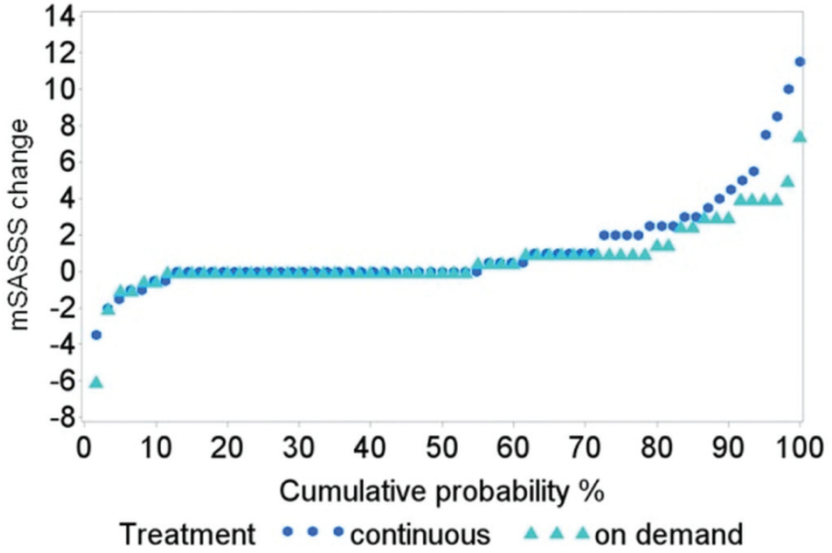
➢ Results:

- mSASSS progression was numerically **higher in the continuous group** compared to the on demand group (1.28; 95%CI 0.68-1.92 vs 0.79; 95%CI 0.17-1.38 in the completer population), although this difference was **not statistically significant**

Figure. Radiographic spinal progression in the completer population (n = 62 in the continuous arm and n = 60 in the on demand arm)



Παγκρήτια Ένωση Υγείας

CONTINUOUS VERSUS ON DEMAND TREATMENT OF ANKYLOSING SPONDYLITIS WITH DICLOFENAC OVER 2 YEARS DOES NOT PREVENT RADIOGRAPHIC PROGRESSION OF THE SPINE – RESULTS FROM A RANDOMIZED PROSPECTIVE MULTI-CENTER TRIAL (ENRADAS)

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➢ **Results:**

- When only patients were analysed who had known risk factors for radiographic progression

✓ **CRP positive at baseline** or

✓ **syndesmophytes at baseline**

again there was numerically a higher radiographic progression in the continuous vs the on demand group

- **No differences** between the 2 treatment groups regarding side effects (**19** VS **19** SAEs)

Παγκρήτια Ένωση Υγείας

CONTINUOUS VERSUS ON DEMAND TREATMENT OF ANKYLOSING SPONDYLITIS WITH DICLOFENAC OVER 2 YEARS DOES NOT PREVENT RADIOGRAPHIC PROGRESSION OF THE SPINE – RESULTS FROM A RANDOMIZED PROSPECTIVE MULTI-CENTER TRIAL (ENRADAS)

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➢ **Conclusions:**

- Neither continuous nor on demand Tx with Diclofenac over 2 years prevented radiographic progression in AS.
- Other NSAIDs such as Celecoxib would have had a different effect**???**

Παγκρήτια Ένωση Υγείας

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Abstract session:

SpA treatment

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ΙΑΤΡΙΚΗ ΣΧΟΛΗ

SECUKINUMAB SIGNIFICANTLY IMPROVES SIGNS AND SYMPTOMS OF ACTIVE ANKYLOSING SPONDYLITIS: 52-WEEK DATA FROM MEASURE 2, A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 TRIAL WITH SUBCUTANEOUS LOADING AND MAINTENANCE DOSING

J.Sieper et al

- **Objectives:** To investigate the long-term (52 wks) efficacy and safety of s.c. secukinumab in the MEASURE 2 study.

- **Methods:**
- 219 adults with active AS, despite NSAIDs
- Randomization to receive s.c. **secukinumab 150 mg, 75 mg, or placebo (PBO)** at baseline, Wk 1, 2, and 3, and every 4 wks starting from Wk 4.
- At Wk 16, subjects in the PBO group were re-randomized to secukinumab 150 mg or 75 mg every 4 wks

Παγκρήτια Ένωση Υγείας

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J.Sieper et al

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- **Primary endpoint**: was the proportion of pts achieving **ASAS 20 response at Wk 16.**
- **Secondary endpoints:**

✓ ASAS40

✓ hsCRP

✓ BASDAI

✓ Short Form-36 Health Survey Physical Component Summary (SF-36 PCS)

✓ Ankylosing Spondylitis Quality of Life (ASQoL)

✓ ASAS partial remission

Παγκρήτια Ένωση Υγείας

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J.Sieper et al

Table: Primary and Secondary Endpoint Results at Weeks 16 and 52

		Secukinumab 150 mg s.c.	Secukinumab 75 mg s.c.	Placebo
ASAS20, %	Wk 16	61.1†	41.1	28.4
	Wk 52	73.8	63.9	N/A
ASAS40, %	Wk 16	36.1†	26.0	10.8
	Wk 52	57.4	41.0	N/A
hsCRP, post-baseline/baseline ratio	Wk 16	0.55†	0.61	1.13
	Wk 52	0.46	0.58	N/A
ASAS 5/6, %	Wk 16	43.1†	34.2	8.1
	Wk 52	62.3	47.5	N/A
BASDAI, mean change from baseline	Wk 16	–2.19†	–1.92	–0.85
	Wk 52	–3.14	–2.63	N/A
SF-36 PCS, mean change from baseline	Wk 16	6.06†	4.77	1.92
	Wk 52	7.99	6.62	N/A
ASQoL, mean change from baseline	Wk 16	–4.00§	–3.33	–1.37
	Wk 52	–5.25	–4.13	N/A
ASAS partial remission, %	Wk 16	13.9	15.1	4.1
	Wk 52	26.2	18.0	N/A

†$P < 0.001$ §$P < 0.01$ for comparisons vs PBO. *P*-values at Wk 16 are adjusted for multiplicity of testing. At Wk 16: n=72 secukinumab 150 mg, n=73 secukinumab 75 mg, n=74 placebo; At Wk 52 (excluding pts initially randomized to PBO): n=61 for both secukinumab 150 mg and 75 mg (except for SF-36 PCS where n=62 and n=58, respectively, and for ASQoL where n=60 for secukinumab 75 mg). NRI (binary variables) and MMRM (continuous variables) data presented at Wk 16. Wk 52 data are as observed, except hsCRP where the post-baseline to baseline ratio is presented. N/A, not applicable

Παγκρήτια Ένωση Υγείας

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J.Sieper et al

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➢ **Adverse events:**

- Most common SAE : **serious infections**
- No subject discontinued therapy due to a SAE

➢ **Conclusions:**

- Secukinumab 150 mg s.c. provided sustained improvements to 52 weeks in the signs and symptoms of AS, reducing inflammation, and improving physical function and health-related quality of life.
- Secukinumab was well tolerated

Παγκρήτια Ένωση Υγείας

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Abstract session:

PsA treatment

Παγκρήτια Ένωση Υγείας

APREMILAST, AN ORAL PHOSPHODIESTERASE 4 INHIBITOR, IS ASSOCIATED WITH LONG-TERM (104-WEEK) IMPROVEMENTS IN ENTHESITIS AND DACTYLITIS IN PATIENTS WITH PSORIATIC ARTHRITIS: POOLED RESULTS FROM THREE PHASE 3, RANDOMIZED, CONTROLLED TRIALS

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

D. Gladman et al

- **Question:** Impact of APR treatment over 104 wks on **enthesitis** and **dactylitis** in a pooled analysis of PALACE 1-3.

- **Methods:** Pts were randomized **(1:1:1) to PBO, APR 20 mg BID (APR20), or APR 30 mg BID (APR30)**

- The PBO-controlled phase continued to Wk 24, with an early escape option at Wk 16.
- Double-blind APR treatment continued to Wk 52
- Pts could then continue to receive APR for up to an additional 4 years during an open-label extension phase.
- Enthesitis was evaluated based on Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) (range 0-13)
- Dactylitis count (range 0-20) is the number of digits with dactylitis present

Παγκρήτια Ένωση Υγείας

APREMILAST, AN ORAL PHOSPHODIESTERASE 4 INHIBITOR, IS ASSOCIATED WITH LONG-TERM (104-WEEK) IMPROVEMENTS IN ENTHESITIS AND DACTYLITIS IN PATIENTS WITH PSORIATIC ARTHRITIS: POOLED RESULTS FROM THREE PHASE 3, RANDOMIZED, CONTROLLED TRIALS

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D. Gladman et al

Enthesitis and Dactylitis at Wk 52 and Wk 104 (Data as Observed)				
	Wk 52		Wk 104	
MASES*	**APR20 n=326**	**APR30 n=377**	**APR 20 n=260**	**APR30 n=302**
BL, mean	4.5	4.4	4.6	4.3
Mean % change from BL	-42.2	-43.5	-55.1	-57.5
Pts achieving score of 0, %	41.1	37.7	51.5	48.7
Dactylitis count§	**APR20 n=225**	**APR30 n=249**	**APR20 n=181**	**APR30 n=200**
BL, mean	3.3	3.4	3.2	3.4
Mean % change from BL	-70.2	-67.9	-75.8	-80.0
Pts achieving score of 0, %	66.7	67.5	72.9	77.5

The n represents the number of pts taking APR (regardless of when treatment started) with a baseline value >0 and a value at Wk 52 or Wk 104. *MASES ranges from 0 to 13, with 0 indicating no pain at any assessed entheses and 13 indicating pain at all assessed entheses. §Dactylitis count is the sum of all scores for each of the 20 digits, with each digit scored as 0=absence or 1=presence of dactylitis.

Conclusions: Over 104 wks, APR continued to demonstrate efficacy in PsA treatment, including improvements in enthesitis and dactylitis. APR demonstrated an acceptable safety profile and was generally well tolerated for up to 104 wks.

Παγκρήτια Ένωση Υγείας

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

EFFICACY AND SAFETY OF USTEKINUMAB IN PSORIATIC ARTHRITIS PATIENTS WITH SPONDYLITIS AND PERIPHERAL JOINT INVOLVEMENT: RESULTS FROM A PHASE 3, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

Kavanaugh et al

- **Objectives: Efficacy of SC UST 45/90 mg** in a subgroup of psoriatic arthritis (PsA) pts with physician diagnosed spondylitis and peripheral joint involvement through wk108, from PSUMMIT 1.

- **Methods:**

- Adult PsA patients (n=615) with active disease (**≥5 SJC and ≥5 TJC;CRP≥0.3mg/dL**) despite DMARD and/or NSAIDs
- Randomization to UST**45**mg**, 90**mg, **or PBO** at wks 0, 4, and q12wks.
- Pts treated with prior anti-TNF agents were excluded.
- Stable concomitant MTX was permitted but not mandated.
- At wk16, pts with *<5% improvement in TJC & SJC entered blinded early escape* (PBO→UST45mg; UST45mg→90mg; 90mg→90mg)
- PBO pts subsequently
- crossed over to UST45mg at wk24.

Παγκρήτια Ένωση Υγείας

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Kavanaugh et al

Results:

- At wk24, greater proportions of combined UST45/90mg treated pts had **improvements in dactylitis/enthesitis measurements, HAQ-DI and ACR20/50/70** responses than PBO
- Clinical improvements were generally maintained through wk100.
- Significantly higher proportion of UST-treated pts achieved **BASDAI20/50/70** responses vs. PBO at wk24 (54.1%/27.9%/14.4% vs. 26.2%/13.1%/0.0%).
- Peripheral structural damage also showed improvement in the UST groups vs PBO
- Discontinuations due to AEs **2.9% vs 0.9%**
- Through 2yrs, safety observations were consistent with the overall PsA population.

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EFFICACY AND SAFETY OF USTEKINUMAB IN PSORIATIC ARTHRITIS PATIENTS WITH SPONDYLITIS AND PERIPHERAL JOINT INVOLVEMENT: RESULTS FROM A PHASE 3, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

Kavanaugh et al

Conclusions:

- In this post-hoc subgroup analysis, UST significantly improved signs and symptoms, and demonstrated improvements in **BASDAI** and **peripheral radiographic progression** compared with PBO through wk24;
- efficacy was maintained through wk100.
- UST was well-tolerated and demonstrated a safety profile similar to that observed in the overall PsA study population.

Παγκρήτια Ένωση Υγείας

TWO-YEAR CLINICAL RESPONSE TO BRODALUMAB, AN ANTI-IL-17 RECEPTOR ANTIBODY, IN PATIENTS WITH PSORIATIC ARTHRITIS (P.Mease et al)

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

- **Objectives: Long-term safety and efficacy of brodalumab in** patients with psoriatic arthritis **(PsA)** in an open-label extension (OLE) of a phase 2 study
- **Methods:**
- Adults with active PsA were randomized to brodalumab **(140 or 280 mg)** or placebo at weeks 0, 1, 2, 4, 6, 8, and 10
- At week 12, patients could enter an OLE and receive brodalumab 280 mg every 2 wks
- Outcome measures:
- **ACR20**
- **ACR50**
- **Changes in ACR components and Psoriasis Symptom Inventory (PSI) score.**
- **Safety (AEs)**

TWO-YEAR CLINICAL RESPONSE TO BRODALUMAB, AN ANTI-IL-17 RECEPTOR ANTIBODY, IN PATIENTS WITH PSORIATIC ARTHRITIS (P.Mease et al)

➢ **Results:**

- Through week 108, **96%** pts reported an AE and **15%** reported SAE.
- Most frequent SAEs**: coronary artery disease, cholelithiasis, and cellulitis**
- Most frequent AEs (≥10% of all patients): nasopharyngitis, upper RTI, psoriatic arthropathy, UTI, arthralgia, diarrhea, sinusitis, and bronchitis.
- No deaths, 1 laboratory report of neutropenia, 1 case of suicidal ideation, and 11 cases of oral candidiasis

Παγκρήτια Ένωση Υγείας

TWO-YEAR CLINICAL RESPONSE TO BRODALUMAB, AN ANTI-IL-17 RECEPTOR ANTIBODY, IN PATIENTS WITH PSORIATIC ARTHRITIS (P.Mease et al)

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

- **Results:**At week 12 of the study (double-blind phase):
- ACR20 :**37**% (140 mg) and **39**% (280 mg) vs **18**% (placebo)
- ACR50: **14**% and **14**% vs **4**%.
- Through week 108 of the OLE, still meaningful clinical benefit in ACR20 and ACR50

- **Conclusions:** Treatment with brodalumab resulted in an **acceptable safety profile** and **meaningful clinical benefit** that was maintained through week 108 in patients with PsA .

Παγκρήτια Ένωση Υγείας

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

Abstract session

PMR/GCA

Παγκρήτια Ένωση Υγείας

FRI0253 **CLINICAL EFFICACY OF TOCILIZUMAB IN POLYMYALGIA RHEUMATICA: AN OPEN-LABEL STUDY**

E. Toussirot et al. (France)

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

- **Objectives:** Efficacy and safety of TCZ in the treatment of patients with isolated PMR who had an inadequate response to CS and/or to other conventional therapies.

- **Methods:**

- 7 cases were declared during a 12 months period (4 men, 3 women)
- mean age 73.4±7.9 years, disease duration 2.3±1.6 years
- mean duration of CS treatment before starting TCZ: 16.1±9.2 months.
- PMR symptoms for all and only one patient had proved associated GCA but without related clinical manifestations
- CS refractory requiring a daily dosage of prednisone ranging from 10 to 20 mg.
- patients had received MTX (6 cases), leflunomide (1 case) or a TNFa blocking agent (2 cases).

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- **Results:** All the patients responded to the treatment
- improvement of the **PMR-AS** score (score before and after TCZ**: 32.3** and **7.8**, respectively)
- **CRP** before and after TCZ: **56.9** and **4.6** mg/L
- **CS dosage** was tapered from **15- 20** mg to **2.5-5** mg (5 cases) or **stopped** (2 cases).
- Clinical and laboratory improvement were obtained within the first 3 months after the onset of TCZ
- The safety was excellent without any adverse event.

- **Conclusions:** As previously reported in GCA, TCZ seems very effective in PMR patients who were unable to taper CS, with a prompt response and a Cs sparing effect.

Παγκρήτια Ένωση Υγείας

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Abstract session

GOUT

Παγκρήτια Ένωση Υγείας

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
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SAT0307 LESINURAD MONOTHERAPY IN GOUT PATIENTS INTOLERANT TO XANTHINE OXIDASE INHIBITORS (LIGHT): A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, 6-MONTH PHASE III CLINICAL TRIAL

A.-K. Tausche et al (GER, N.Zealand, USA)

- **Background: Lesinurad** (LESU; RDEA594) is a selective uric acid reabsorption inhibitor (SURI) being investigated for the treatment of gout in combination with a xanthine oxidase inhibitor (XOI).

- **Objectives: LIGHT** is a multinational randomized, double-blind, placebocontrolled**,** 6-month phase III clinical trial to determine the efficacy and safety of LESU 400mg monotherapy in patients intolerant to an XOI
- **Methods**: Gout patients with intolerance/contraindication to XOI and serum uric acid **(sUA) ≥6.5 mg/dL** were randomized to LESU (400mg/d) or placebo (PBO).
- **Primary endpoint** : proportion of patients **with sUA *<6.0 mg/dL at Month 6.***
- *Safety assessments included treatment-emergent* adverse events (TEAEs) and laboratory data.
- Patients who completed the study were eligible to enroll in an open-label, uncontrolled extension study of LESU 400 mg monotherapy

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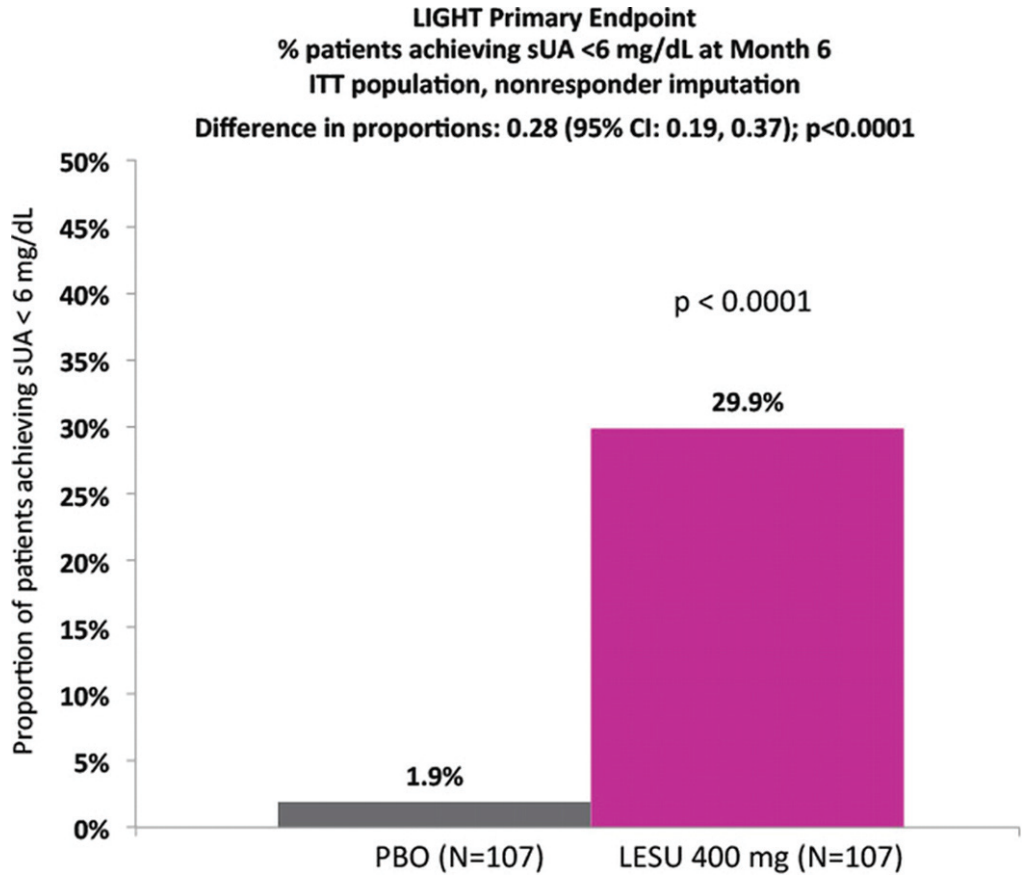
- **Results:** Significantly more patients achieved the primary endpoint (sUA *<6.0 mg/dL at Month 6) with LESU 400mg than PBO* (**29.9% vs.1.9%)**



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A.-K. Tausche et al. (GER, N.Zealand, USA)

➢ **Results:**

- Discontinuation rate was greater with LESU 400mg (**32.7%**) than PBO (**15.9%**).
- Overall AE rate was higher with LESU 400mg, mainly due to more renal AEs

	Core Study		Extension
	PBO (N=107)	LESU400 (N=107)	LESU400 (N=143*)
Patients experiencing any TEAE	70 (65.4%)	83 (77.6%)	105 (73.4%)
Patients with serious TEAEs	4 (3.7%)	9 (8.4%)	15 (10.5%)
Patients with renal-related AEs	0 (0%)	19 (17.8%)	24 (16.8%)
Patients with serious renal-related AEs	0 (0%)	5 (4.7%)	2 (1.4%)
Patients with kidney stones	0 (0%)	1 (0.9%)	6 (4.2%)
Patients with ≥2.0x increase in sCr	0 (0%)	9 (8.4%)	9 (6.3%)
Number (%) sCr elevations resolved at last study visit	–	6/11 (54.5%)	6/10 (60%)

- **Conclusions:** In this multinational study of gout patients with high sUA and intolerance/ contraindication to an XOI**, nearly one third of patients treated with LESU 400 mg achieved sUA *<6 mg/dL at 6 months***. *Renal AEs were more* frequent with LESU 400mg monotherapy.

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Abstract session

OSTEOPOROSIS

Παγκρήτια Ένωση Υγείας

DENOSUMAB TREATMENT IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS FOR UP TO 9 YEARS: RESULTS THROUGH YEAR 6 OF THE FREEDOM EXTENSION

S. Papapoulos et al

ΠΑΝΕΠΙΣΤΗΜΙΟ ΚΡΗΤΗΣ
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- **Background:** Denosumab treatment was shown to decrease the risk of vertebral and nonvertebral fracture in postmenopausal women with osteoporosis in the 3-year FREEDOM trial.
- The 7-year FREEDOM Extension is an open-label study to evaluate the long-term safety and efficacy of denosumab treatment for up to 10 years

- **Objectives:** To report the results through year 6 of the FREEDOM open-label Extension, representing up to 9 years of continued denosumab for the treatment of postmenopausal osteoporosis
- **Methods:**
- All women received 60 mg denosumab every 6 months, and daily calcium and vitamin D
- At Extension year 6, bone turnover markers, nonvertebral fracture incidence, and adverse events were evaluated.
- Women in the long-term group received up to 9 years of denosumab (3 years in FREEDOM and up to 6 years in the Extension)
- Women in the cross-over group received up to 6 years of denosumab (3 years of placebo in FREEDOM and up to 6 years of denosumab in the Extension)

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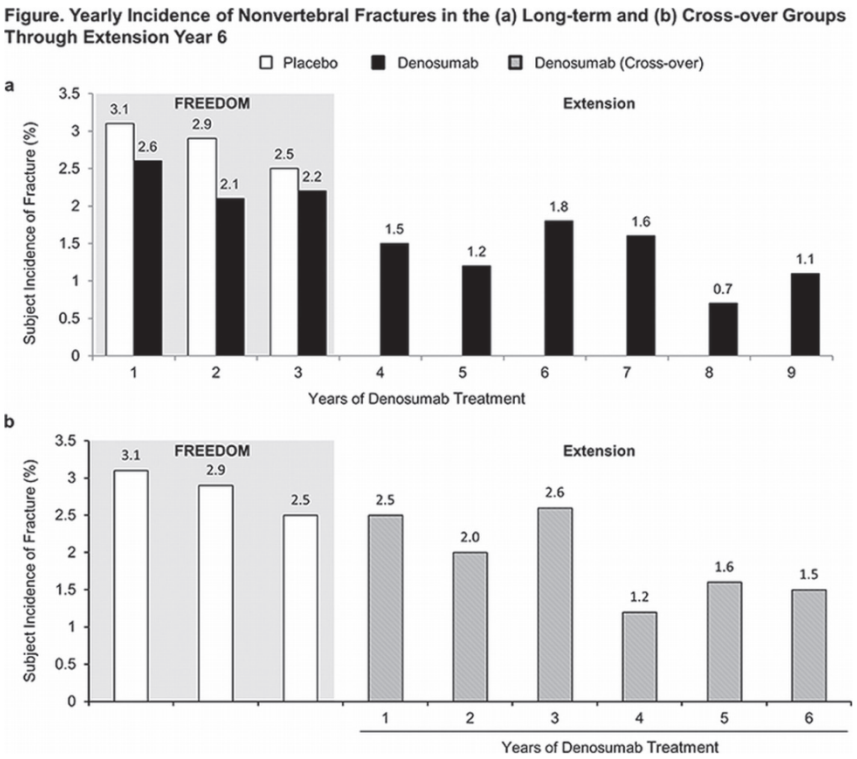
➢ **Results:**

- In both groups, serum CTx and P1NP were similarly reduced after each denosumab dose.
- Reductions were sustained through Extension year 6.
- The yearly incidences of nonvertebral and major nonvertebral fractures remained low in both groups
- 2 events were adjudicated positive for ONJ in the cross-over group
- No cases of atypical femoral fracture in either group.



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- **Conclusions:** In this aging population, denosumab treatment for up to 9 years maintained reduced bone turnover and was associated with continued low incidence of nonvertebral and major nonvertebral fractures. The benefit/risk profile remained favorable