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The EULAR Journal

Annual European Congress of RHEUMATOLOGY

EULAR 2017

Madrid, 14–17 June 2017

Abstracts

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Welcome Address

Dear Colleagues,

Welcome to this EULAR Annual European Congress of Rheumatology in Madrid!
Welcome to the 70th anniversary of EULAR!

The annual EULAR Congresses, which began in 2000, are today a major event in the calendar of world rheumatology. This meeting, which marks the 70th anniversary of our very active society, will once again provide a unique occasion for the exchange of scientific and clinical information. It will facilitate interaction between patients, medical doctors, scientists, health professionals and professionals representing the pharmaceutical industry from Europe and from around the world. Participating in the congress is just one element of the annual educational package provided by EULAR: Almost all oral presentations will be available online after signing up and participants will be provided with a complimentary, one-year subscription to the latest developments and publications in the field of rheumatic and musculoskeletal diseases (RMDs). This is in line with a new, exciting event taking place in Madrid this year – the launch of the EULAR School of Rheumatology, which will be unique in providing education in rheumatology throughout the world.

EULAR has grown rapidly in terms of the number of participants and the quality of the submissions. A record number of more than 4'850 abstracts have been submitted to this year's congress in Madrid, and 180 sessions and poster tours are offered. This tremendous success continues to reflect the increasing interest in RMDs; it also reflects the availability of increased information on the size, burden and cost of these diseases for society – and a significantly improved ability to diagnose and treat them. The incorporation of health professional and patient organisations within EULAR has been a considerable stimulus for these advances.

The EULAR Congress 2017 in Madrid will provide a wide range of topics including clinical innovations, clinical translational and basic science. In addition, there will be significant contributions made by People with Arthritis and Rheumatism (PARE), by Health Professionals in Rheumatology (HPR) and by the health care industry. The core science and central activity of the congress will be the poster presentations and poster tours with their highly interactive exchanges between participants. The Madrid meeting will further promote the reputation of the EULAR Congress as a most innovative and informative venue for clinical research for the practising physician and health professionals. Meanwhile, the EULAR EMEUNET organisation of young rheumatologists aims to attract young colleagues to the meeting and will disseminate the message that rheumatology is one of the most attractive and successful disciplines of medicine.

We are back in the vibrant city of Madrid with its remarkable history, architecture, galleries, museums and ambience, all of which will once again provide an excellent background for clinical exchanges, international collaborations and renewal of friendships. "No pierdas tu tren" and in international language "Don't Delay, Connect Today!" marks the first general EULAR Campaign to be launched in Madrid aiming at early recognition and treatment of RMDs.

It is our great pleasure and a real joy in welcoming medical doctors, patients, health professionals and representatives of the pharmaceutical industry and we hope their stay in Madrid will be delightful, informative, and educational. We wish you a great time, good science, good discussions, good meetings and most of all good memories to take home when you are heading back from Madrid and from our 70th anniversary congress.

Gerd R. Burmester
President of EULAR

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FRIDAY, 16 JUNE 2017

Rheumatoid arthritis - anti-TNF therapy

FRI0178 RITUXIMAB IS EFFECTIVE IN THE TREATMENT OF RHEUMATOID ARTHRITIS REGARDLESS OF BODY MASS INDEX

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Background: High body mass index (BMI) is known to be associated with inadequate clinical response to anti-TNF agents in rheumatoid arthritis (RA) patients.[1] However, there are limited data on the effect of high BMI on the response to rituximab in RA patients, who showed an inadequate response or intolerance to anti-TNF agents.
Objectives: To investigate the impact of BMI on clinical response in the post-hoc analysis of randomized controlled trial that demonstrated clinical equivalence between a biosimilar of rituximab, CT-P10 and innovator rituximab, RTX[2] (NCT02149121).
Methods: A total of 332 patients who received two courses of either CT-P10 or RTX were included in this analysis. Patients were classified into 3 groups; normal weight (<25kg/m^2), overweight (≥25 kg/m^2 ~<30 kg/m^2) and obesity (≥30 kg/m^2) as per WHO BMI category. Improvement in disease activity by the Disease Activity Score using C-reactive protein (DAS28-CRP), remission (≤2.6), low disease activity rate (LDA, ≤3.2) and ACR response at Week 24 (Week 24 of 1st course) and Week 48 (Week 24 of 2nd course) and duration of sustained LDA (from the first LDA observed to the last LDA observed up to Week 48) were analysed by BMI categories in the each and combined group of CT-P10 and RTX.
Results: In the pooled group of CT-P10 and RTX, the mean weights were 59 kg in normal weight, 73kg in overweight and 91kg in obesity. All other baseline characteristics were comparable among BMI groups including baseline disease activity based on DAS28; Moderate disease activity, 22.3% vs. 22.8% vs. 25.7%, respectively; High disease activity, 77.7% vs. 77.2% vs. 74.3%, respectively. There was no statistical difference among BMI groups in terms of DAS28 change from baseline and ACR 20/50/70 response (Table). No particular trend was observed in remission and LDA rate by DAS28 at Week 24 and Week 48 among BMI groups (Figure). Mean duration of sustained LDA (months) were also comparable among the groups (4.5 vs. 4.7 vs. 5.0, respectively). Additionally, similar trends in all analyses were observed in each treatment group; CT-P10 and RTX.
Conclusions: The BMI does not affect the clinical response in RA patients with rituximab treatment. Therefore, this result supports that rituximab could be a reasonable therapeutic option for obese RA patients with inadequate response to anti-TNF agents.

Table 1. DAS28, ACR responses by BMI subgroups

Parameter	Visit	Normal (N=148)	Over weight (N=114)	Obesity (N=70)
DAS28, mean (SD)	Baseline	5.88 (0.95)	5.81 (0.89)	5.69 (0.78)
	Week 24*	-2.43 (1.12)	-2.13 (1.19)	-2.39 (0.99)
	Week 48*	-2.76 (1.31)	-2.47 (1.32)	-2.74 (1.01)
ACR20, n (%)	Week 24	122 (82.4%)	86 (75.4%)	56 (80.0%)
	Week 48	119 (80.4%)	88 (77.2%)	60 (85.7%)
ACR50, n (%)	Week 24	80 (54.1%)	56 (49.1%)	39 (55.7%)
	Week 48	76 (51.4%)	62 (54.4%)	43 (61.4%)
ACR70, n (%)	Week 24	51 (34.5%)	33 (28.9%)	21 (30.0%)
	Week 48	47 (31.8%)	36 (31.6%)	26 (37.1%)

*Change from baseline.

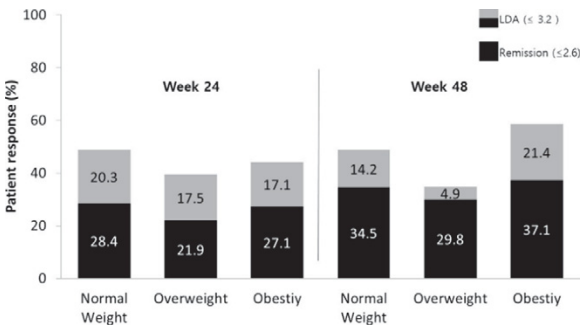

Figure 1. Remission and LDA by DAS28 by BMI group.

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FRI0179 MINIMAL TO NO TRANSFER OF CERTOLIZUMAB PEGOL INTO BREAST MILK: RESULTS FROM CRADLE, A PROSPECTIVE, POSTMARKETING, MULTICENTER, PHARMACOKINETIC STUDY

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Background: Women with active chronic rheumatic inflammatory conditions (RA, PsA, AxSpA) often face uncertainty regarding the safety of the use of biologics during breastfeeding.[1] Limited and non-validated data exist on the potential transfer of anti-TNFs into breast milk.[2] CRADLE (NCT02154425) was the first sponsored study to evaluate certolizumab pegol (CZP) concentrations in breast milk, and to estimate the Average Daily Infant Dose (ADID) of maternal CZP.
Objectives: To determine the concentration of CZP in breast milk and calculate the ADID of maternal CZP.
Methods: CRADLE was a pharmacokinetic study of lactating mothers (≥6 weeks postpartum) receiving commercial CZP. Decision to treat with CZP and breastfeed was independent of study participation. At steady state (≥3 CZP doses), breast milk samples were collected on Days 0, 2, 4, 6, 8, 10, 12, 14 (±28) from each mother across 1 dosing period. CZP was detected using a highly sensitive, CZP-specific electrochemiluminescence immunoassay validated in milk (lower limit of quantification [LLOQ]=0.032 μg/mL; 10-fold lower than previous assays). CZP stability in milk was confirmed.
Results: 18 CZP-treated mothers were screened: 17 entered the sampling period; 16 on CZP 200 mg Q2W; 1 on CZP 400 mg Q4W (7 RA; 5 SpA; 5 CD; Table A). Samples from 4/17 mothers had no measurable CZP in breast milk; 13/17 had quantifiable levels for at least 1 time point (highest concentration: 0.076 μg/mL; Table B). Estimated ADID ranged 0–0.0104 mg/kg/day; median Relative Infant Dose (RID; calculated post hoc[3]): 0.15%. Infants of CZP-exposed mothers had a

Table A: Baseline characteristics of mothers and infants

Mean (SD), unless otherwise stated	All mothers (N=18) [a]
Age, years	33.7 (4.2)
Weight, kg	68.9 (9.6)
BMI, kg/m²	23.6 (3.0)
Indication for CZP treatment, n [b]	
Rheumatoid arthritis	7
Psoriatic arthritis	3
Axial spondyloarthritis/ankylosing spondylitis	2
Crohn's disease	5
Infant age at mother's first sample, n (%)	**All infants (N=17)**
≤6 months	13 (76.5)
>6 months–≤12 months	2 (11.8)
>12 months–≤18 months	2 (11.8)

[a] Includes 1 screen failure; [b] n=17.

Table B: Concentrations of CZP (μg/mL) in breast milk

Mother no.	Relative time (days) 0	2	4	6	8	10	12	14	28
5	0.056	0.069	0.074	0.076	0.076	0.069	0.069	0.06	–
1	0.057	0.051	0.066	0.065	0.062	0.056	0.052	0.041	–
9	0.039	0.04	0.047	0.045	0.042	0.043	0.038	0.035	–
3	BLQ	0.032	0.049	0.053	0.037	0.037	0.033	0.033	–
16	0.04	0.033	0.036	0.037	0.043	BLQ	BLQ	BLQ	–
11	BLQ	BLQ	0.051	0.038	0.042	BLQ	0.033	BLQ	–
2	BLQ	BLQ	0.035	0.037	0.041	BLQ	0.043	BLQ	–
15	BLQ	BLQ	0.041	0.034	0.033	BLQ	0.037	BLQ	–
10	BLQ	BLQ	BLQ	0.033	0.042	0.042	BLQ	BLQ	–
8	BLQ	BLQ	0.035	0.034	0.043	BLQ	BLQ	BLQ	–
12	BLQ	BLQ	0.034	0.037	0.033	BLQ	BLQ	BLQ	–
6	BLQ	BLQ	0.044	0.048	BLQ	BLQ	BLQ	BLQ	–
7	BLQ	BLQ	BLQ	BLQ	BLQ	0.035	BLQ	BLQ	–
4	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	–
13	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	–
14	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	–
17	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ	BLQ

Less than 3×LLOQ (<0.096 μg/mL)
Less than 2×LLOQ (<0.064 μg/mL)
BLQ (<0.032 μg/mL)
CZP plasma C_{trough} from the RAPID2 study: 15.7 μg/mL

BLQ: below the lower limit of quantification; LLOQ: lower limit of quantification.

Table 1. Description of psychiatric symptoms registered in the database for TNF-α inhibitors

Characteristics	Patients (Total = 71)
Major psychiatric symptoms:	11 (15%)
– Manic episode	8 (11%)
– Acute psychosis	3 (4%)
Minor psychiatric symptoms:	60 (85%)
– Anxiety/Nervousness	10 (14%)/6 (8%)
– Insomnia or decreased need for sleep	31 (44%)
– Psychomotor agitation/Aggressiveness	6 (8%)/8 (11%)
– Hallucinations	7 (10%)
– Libido exacerbation	2 (3%)
– Euphoria, grandiosity	4 (6%)
– Derealization, depersonalization	3 (4%)
Psychiatric side effect improved:	45 (63%)
– TNF-α Inhibitors withdrawn	32 (45%)
– TNF-α Inhibitors not withdrawn	9 (13%)
– Missing data	4 (6%)
Psychiatric side effect did not improved:	16 (22%)
– TNF-α Inhibitors withdrawn	8 (11%)
– TNF-α Inhibitors not withdrawn	4 (6%)
– Missing data	3 (4%)
Missing data improved/not improved	10 (14%)

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SAT0145 INFLUENCE OF BODY MASS INDEX (BMI) ON THE DISEASE INFLAMMATORY ACTIVITY AND TREATMENT REPONSE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: The use of biological therapy (BT) in rheumatoid arthritis (RA) has supposes a very important change in the disease's treatment and prognosis. Drugs like Anti-TNFα have proven unquestionable effectiveness. However, the lack or loss of such effectiveness over time raises the dilemma of what factors may influence it. There are studies that suggest the influence of BMI on the efficacy of these drugs and therefore on the control of the disease.
Objectives: To determine the influence of BMI on disease activity and response to treatment with infliximab (ifx) in patients with RA.
Methods: A retrospective observational study of a population of 76 patients with RA who received infliximab treatment, in a standard guideline of 3 mg/kg, in our service between 2000 and 2016 inclusive. The BMI was classified for some sub-studies in four categories: low (<18.5), normal (=18.5- <25), overweight (=25- <30) and obesity (=30). Disease activity was determined by DAS28 at three times: at baseline, at 6 months and at the year of infliximab treatment; Response to treatment was assessed by deltaDAS28 and EULAR response at 6 months and 1 year of treatment. The EULAR response was classified into two categories: "yes" (DeltaDAS28>1.2, or>0.6 and DAS28 <5.1) and "no" (DeltaDAS28 <.6, or <5.1). First, activity and response rates to treatment were compared in these four groups over the three periods. A regression analysis was then performed for BMI and both activity and response to treatment.
Results: Characteristics of the 76 patients included in the study when initiating IFX therapy were: 66 (86.8%) were women, median (range) age 54 (21–83) years, 77,% RF+, 81% ACPA+, disease duration 10,8 (1,0–39,0) years, 59% with concomitant methotrexate and 55% with other DMARDs. Median (range) BMI was 25,5 (16,7–40,2) kg/m^2. According to BMI, patients with underweight, normal, overweight and obesity were 0 (0,0%), 41 (53,9%), 22 (28,9%) and 13 (17,2%), respectively. The association between BMI and disease activity (median DAS28 (p25-p75)) is shown in Table 1:

Table 1

	Normal	Overweight	Obesity
DAS28 bas	5,63 (4–84–6,30)	5,44 (4,45–6,73)	6,25 (4,42–7,07)
DAS28 6m	3,90 (2,89–5-12)	3,97 (3,32–5,43)	4,80 (3,35–5,72)
DAS28 1y	3,91 (2,89–5,01)	3,69 (2,97–5,29)	4,48 (2,70–5,87)

The association between BMI and treatment response (median deltaDAS28 (p25-p75) and EULAR response (%)) is shown in Table 2:

Table 2

	Normal	Overweight	Obesity	*p*
ΔDAS28				
ΔDAS28 0–6m	1,72 (0,84–2,77)	1,39 (0,38–2,49)	0,77 (0,40–1,59)	*0,2*
ΔDAS28 0–1y	1,56 (0,81–2,74)	1,77 (,092–2,92)	1,20 (0,73–1,90)	*0,2*
EULAR response 6m	70,7	68,2	30,8	*0,065*
EULAR response 1y	61,0	54,5	61,5	*0,065*

In the longitudinal analysis, a trending but not statistically significant relationship between adjusted BMI and DAS28 was observed at six month and at one year of treatment onset: β: 0,051; 95% CI (-0,06 to 0,109) and β: 0,037; 95% CI (-0,022 to 0,097)

Conclusions: BMI seems to influence, in a non significantly manner, in disease activity and in treatment response in RA treated with infliximab. Obesity BMI values are associated with increased activity and a lower response to this treatment than lower BMI values.
Disclosure of Interest: None declared
DOI: 10.1136/annrheumdis-2017-eular.4449

SAT0146 RANDOMISED DOUBLE-BLIND STUDY SHOWS COMPARABLE LONG-TERM EFFICACY AND SAFETY BETWEEN RITUXIMAB BIOSIMILAR CT-P10 AND INNOVATOR RITUXIMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS: 48-WEEK RESULTS

C.-H. Suh[1], E. Chalouhi El Khouri[2], P. Miranda[3], F. F Cons Molina[4], P. Shesternya[5], F. Medina-Rodriguez[6], P. Wiland[7], S. Jeka[8], J. Chavez-Corrales[9], T. Linde[10], P. Hrycaj[11], I. Hospodarskyy[12], M. Abello-Banfi[13], J. Jaworski[14], M. Piotrowski[15], W. Park[16], S.C. Shim[17], S.J. Lee[18], S.Y. Lee[18], D.H. Yoo[19]. *[1]Ajou University School of Medicine, Suwon, Korea, Republic Of; [2]Clinica Internacional, Lima, Peru; [3]Centro de Estudios Reumatológicos, Santiago, Chile; [4]Centro de Investigacion en Artritis y Osteoporosis, Mexicali, Mexico; [5]KrasSMU, Krasnoyarsk, Russian Federation; [6]Biologics Especializados SA, Mexico City, Mexico; [7]Medical University, Wroclaw; [8]2nd University Hospital, CM UMK, Bydgoszcz, Poland; [9]Clinica San Borja, Lima, Peru; [10]Rheumatology Medical Center, Halle/Saale, Germany; [11]Poznañ University of Medical Sciences, Poznañ, Poland; [12]Ternopil Medical University, Ternopil, Ukraine; [13]Centro Integral de Reumatologia del Caribe, Barranquilla, Colombia; [14]Reumatika - Centrum Reumatologii, Warszawa; [15]Medical University of Lublin, Lublin, Poland; [16]IN-HA University, School of Medicine, Incheon; [17]Chungnam National University Hospital, Daejeon; [18]Celltrion, Inc., Incheon; [19]Hanyang University Hospital for Rheumatic Diseases, Seoul, Korea, Republic Of*

Background: In phase 1 trials (NCT01534884 and NCT01873443), pharmacokinetic equivalence of CT-P10, biosimilar of rituximab, to innovator rituximab (RTX) was demonstrated. In the phase 3 study, equivalence of PK and efficacy up to week 24 were achieved between CT-P10 and RTX (US and EU sourced)[1,2].
Objectives: To investigate the long-term efficacy, pharmacodynamics, immunogenicity and safety of CT-P10 up to week 48.
Methods: Patients with rheumatoid arthritis were randomly assigned to CT-P10, US-RTX or EU-RTX, in combination with MTX. The patients received 2 treatment courses at Week 0 and 24, each consisting of 2 infusions of 1000mg study drug at 2-week interval.
Results: A total of 372 patients were randomised, and 330 patients completed the 2nd course treatment. DAS28 scores through Week 48 were comparable between CT-P10 and US/EU-RTX (Figure), as well as the proportion of ACR responses at Week 48 between the CT-P10 and combined rituximab groups; 81.3% and 79.8% for ACR 20, 55.4% and 53.9% for ACR50, and 31.7% and 33.7% for ACR 70, respectively.

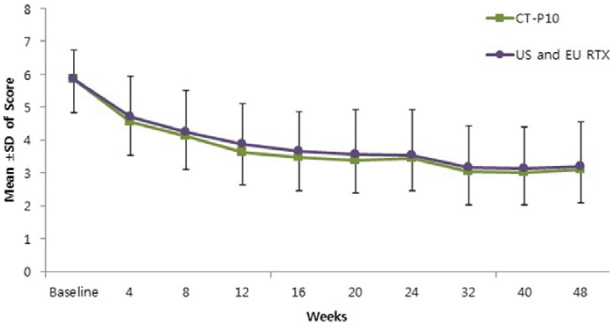

Figure 1. Efficacy Results – DAS28.

B-cell depletion was comparable from after the 1st infusion and up to Week 48. Number (%) of patients with positive anti-drug antibodies in the CT-P10, US-RTX, and EU-RTX was 7 (4.9), 13 (9.4), and 5 (8.6), respectively at Week 48.
The safety profile was also similar across groups (Table).

Table 1. Summary of Safety Profile [n (%)]

	CT-P10 (N=161)	US-RTX (N=151)	EU-RTX (N=60)	Reference Products (US-RTX + EU-RTX) (N=211)
AE	122 (75.8)	96 (63.6)	37 (61.7)	133 (63.0)
Serious Adverse Event	13 (8.1)	14 (9.3)	2 (3.3)	16 (7.6)
Infection	61 (37.9)	53 (35.1)	17 (28.3)	70 (33.2)
Serious infection	2 (1.2)	3 (2.0)	0	3 (1.4)
Infusion related reaction (IRR)*	33 (20.5)	12 (7.9)	13 (21.7)	25 (11.8)
Malignancy	0	2 (1.3)	1 (1.7)	3 (1.4)
Progressive multifocal leukoencephalopathy	0	0	0	0

*None of IRR were serious or led to study drug discontinuation.