

Results: 1040 subjects with 3719 follow-up visits spanning an average of 63.2 weeks were analysed. African Americans and Hispanics comprised 24% and 15%, respectively. Compared to Whites, African Americans and Hispanics had significantly less education ($p<0.001$ for both), significantly less biologic use ($p<0.001$ for both) and significantly less TNF use ($p<0.001$ for both). African Americans had significantly higher RAPID3 scores at enrollment than Whites as well ($p=0.018$).

Switching between TNFi and non-TNFi was recorded in only 9 subjects, with 7 subjects switching from TNFi to non-TNFi. There was no statistical difference between race/ethnic groups in frequency of bDMARD switching, nor within bDMARD class (TNFi class, $p=cc$; non-TNFi class, $p=bb$). bDMARD treatment led to MCI in RAPID3 in 101 (38%) subjects and in more African Americans (29 [48%]) and Hispanics (12 [41%]) than in Whites (49 [37%]) (but not statistically significant).

Conclusions: In our cohort, disparity was seen in bDMARD use between race and ethnic groups but had similar and infrequent biologic switch. Based upon these data, efforts to eliminate biologic use disparity remains paramount and supersedes concerns regarding disparity in biologic switching.

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AB0441 DRUG SURVIVAL AND REASON FOR DROP-OUT IN RHEUMATOID ARTHRITIS PATIENTS WITH A NON-MEDICAL SWITCH FROM ORIGINATOR TO BIOSIMILAR ETANERCEPT – PRELIMINARY DATA FROM A NORWEGIAN MULTICENTER STUDY

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Background: Norwegian rheumatologists are encouraged to prescribe the low-cost priced biologic DMARDs according to the national tender system. Thus, non-medical switch from the originator drug to its biosimilar is extensively performed. There is a need for more real life data to clarify the clinical outcomes, dropout rates and reasons for these dropouts after a non-medical switch from the originator to biosimilar ETN.

Objectives: To explore drug survival and clinical outcomes in rheumatoid arthritis (RA) patients after a non-medical switch from the originator to biosimilar ETN (SB4) in ordinary outpatient clinics across Norway.

Methods: Herein we present preliminary data collected at one participating centre. Patients were monitored and data were collected by the use of a hospital clinical computer system GoTreatIT Rheuma. The computer system is also used for data collection for the Norwegian national arthritis registry, NorArtritt. Demographic, clinical and treatment data were retrieved (21st of January 2018) from the computer system for the time point of non-medical switch of ETN and the last follow up. Wilcoxon matched-pair signed rank test was used for comparison between the two-time points.

Results: Since April 2016 191 RA patients (mean age 60.8 years, 67% females) underwent a non-medical switch from originator to biosimilar ETN. Mean (SD) observation time for the 163 patients (85.3%) still on biosimilar ETN was 1.23 (0.46) yrs. 28 patients (14.7%) stopped treatment. Among them mean (SD) observation time for the 7 patients (3.7%) in remission was 0.53 (0.33) yrs, for the 10 patients (5.2%) reporting adverse events 0.44 (0.32) yrs and for the 11 patients (5.8%) reporting lack or loss of efficacy 0.44 (0.35) yrs. The adverse events reported was: 1 chest pain, 1 neuropathy, 1 GI reaction, 1 visual impairment, 1 infection, 2 joint stiffness (1 patient went back on ETN SB4) and 3 skin reactions. For all 191 patients no significant change (median [IQR]) from baseline to last observation was seen for DAS28 (2.1 [1.5–2.8] vs 1.9 [1.5–2.5], $p=0.33$), MHAQ (0.3 [0.0–0.7] vs 0.4 [0.1–0.6], $p=0.62$) and patient VAS global (20.0 [10.0–43.0] vs 25.0 [10.0–43.3] mm, $p=0.73$), whereas CRP improved significantly during follow up (2.0 [1.0–5.0] vs 1.0 [1.0–5.5] mg/dl, $p=0.02$). For the subgroup of RA patients who stopped treatment because of lack of efficacy a minor non-significant impairment was observed for DAS28 (2.0 [1.4–2.5] vs 2.6 [1.2–4.0], $p=0.32$), CRP (0.0 [0.0–6.0] vs 3.5 [0.8–13.3] mg/dl, $p=0.66$), MHAQ (0.1 [0.0–0.1] vs 0.5 [0.3–0.5], $p=0.66$) and patient VAS global (20.0 [10.0–30.0] vs 29.0 [17.0–58.5] mm, $p=0.66$).

Conclusions: Our preliminary data indicate that for the majority of patients, a non-medical switch from originator to biosimilar ETN (SB4) was well tolerated with no impairment in disease measures. Whether the reported adverse events were associated to the switch needs to be further studied. In patients who stopped the biosimilar because of lack of effect only a minor numerically increase in disease

measures was seen. Our promising preliminary results need to be confirmed in a large scale study.

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AB0442 LONG-TERM SAFETY AND EFFICACY OF BIOSIMILAR INFLIXIMAB (CT-P13) AFTER SWITCHING FROM ORIGINATOR INFLIXIMAB: RESULTS FROM THE 26-WEEK OPEN LABEL EXTENSION OF A NORWEGIAN RANDOMISED TRIAL

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Background: The NOR-SWITCH study was funded by the Norwegian government to investigate if switching from originator infliximab (INX) to biosimilar CT-P13 is safe in rheumatoid arthritis (RA), spondyloarthritis (SpA), psoriatic arthritis (PsA), Crohn's disease (CD), ulcerative colitis (UC), and chronic plaque psoriasis (Ps).

Objectives: Assessing efficacy, safety, immunogenicity at week 78 in patients on CT-P13 for 78 weeks (maintenance group) vs CT-P13 for 26 weeks (switch group).

Methods: 481 adult patients on stable originator infliximab were randomised 1:1 to continued INX or switch to CT-P13 treatment in the main study¹. All extension participants received CT-P13. The primary endpoint was disease worsening, analysed with logistic regression, adjusted for diagnosis and treatment duration.

Abstract AB0442 – Table 1

| Demographic and baseline characteristics (52 w) Number of patients (FAS) | Maintenance group 197 | Switch group 183 | Data are n (%) or mean (SD) |
|---|--------------------------|---------------------|---------------------------------|
| Age (years) | 48.8 (14.9) | 48 (14.3) | |
| Duration of ongoing infliximab treatment (years) | 7.7 (3.8) | 7.4 (3.5) | |
| Concomitant immunosuppressive therapy | 97 (49%) | 75 (41%) | |
| Rheumatoid arthritis | 27 (14%) | 28 (15%) | |
| Spondyloarthritis | 38 (19%) | 29 (16%) | |
| Psoriatic arthritis | 9 (5%) | 11 (6%) | |
| Crohn's disease | 65 (33%) | 62 (34%) | |
| Ulcerative colitis | 42 (21%) | 38 (21%) | |
| Psoriasis | 16 (8%) | 15 (8%) | |
| Disease characteristics | | | |
| DAS 28 RA | 2.4 (0.9) | 2.8 (0.9) | |
| DAS 28 PsA | 2.1 (1.1) | 2.9 (1.8) | |
| ASDAS (SpA) | 1.9 (0.8) | 1.7 (0.7) | |
| Disease worsening | | | |
| Number of patients (PPS) | 190 | 173 | Risk difference (95% CI) |
| All | 32 (16.8%) | 20 (11.6%) | –5.9% (–12.9–1.1) |
| Rheumatoid arthritis | 9 (34.6%) | 6 (22.2%) | –10.5% (–34.6–13.6) |
| Spondyloarthritis | 3 (7.9%) | 2 (7.1%) | –0.6% (–13.5–12.2) |
| Psoriatic arthritis | 1 (12.5%) | 3 (33.3%) | 20.8% (–17.6–59.1) |

ASDAS, Ankylosing Spondylitis Disease Activity Score. DAS28, Disease Activity Score in 28 joints.

Results: 380 patients entered the extension trial. Demographic and baseline (52 w) characteristics of the extension study population are shown (table 1). Disease worsening in the study arms (Per Protocol Set, PPS) and in each diagnosis (explorative analyses) are shown (table 1). Generic disease variables, disease specific composite measures, trough drug levels, anti-drug antibodies and reported adverse events were comparable between groups (data not shown).

Conclusions: We found no difference between patients switched from INX to CT-P13 vs those on maintained CT-P13

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AB0443 THE EFFECTS OF DENOSUMAB FOR RHEUMATOID ARTHRITIS PATIENT

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Background: Denosumab (dMAB), an anti-receptor activator of nuclear factor kappa-B ligand (RANKL) monoclonal antibody, is now popular anti bone absorption suppressant for osteoporosis. Recently, this drug has indicated for rheumatoid arthritis (RA) treatment, for expectance for suppressant in joint destruction. However, except of the effect on joint deformation, anti inflammation effect is not evident in randomised control trial (RCT), although rich case series for OP in RA patient is already collected in clinical practice.

Objectives: Aim of this study is to investigate effects of dMAB on RA, and evaluate other effects but joint destruction suppression.

Methods: In 352 patients who have been treated with dMAB, RA patients who have been treated with dMAB consecutively for more than 1 year, were picked up for this study. Patient who have had experience of biologic disease modifying anti rheumatic drug (bDMARD) or targeted synthetic DMARD, had been eliminated. In whom bone mineral density (BMD) in lumbar spine (LS), femoral neck (FN), and greater trochanter (GT), and tartrate-resistant acid phosphatase 5b (TRACP5b), 28-joints disease activity score with C-reactive protein (DAS28-CRP), Health Assessment Questionnaire Disease Index (HAQ-DI), yearly progression of Sharp/van der Heijde score (dSHS), joint space narrowing score (dJSN) and bone erosion score (dBE), and pain score with visual analogue scale (PS-VAS) were measured, and their mean values were compared between 6 months before start (BEF) and 6 months after start (AFT) statistically with paired T-test. Statistically significant level was set less than 1%.

Results: One hundred and three patients, in whom 100 were female and three were male, were donated in this study. All of them had been supplemented with Denotas Chewable Combination Tablets (Daiichi Sankyo Co., Ltd; Tokyo, Japan), which is medical compound with calcium and natural vitamin D₃. Average age at start was 71.17 years old, and disease duration of RA at start was 7.42 years. Glucocorticoid was administered in 45 patients (44.7%), and methotrexate was administered in 72 patients (69.9%). BMD demonstrated from 74.03 (%YAM) to 77.32 in LS, whereas from 69.79 to 69.63 in FN, and from 71.99 to 74.27 in GT, from BEF to AFT, respectively. BMD of LS and GT at AFT demonstrated significant increase, while FN demonstrated no significant difference. TRACP5b demonstrated 489.3 at BEF, while 255.3 at AFT. TRACP5b at AFT demonstrated significant less value than at BEF. Disease activity, namely DAS28-CRP, tenderness joint count (TJC), swollen joint count (SJC), patient's global assessment (PGA), evaluator's global assessment (EGA), CRP, pain score with visual analogue scale (PS-VAS), HAQ-DI, SHS, JSN, and BE from BEF to AFT demonstrated 2.12 to 1.86, 1.32 to 0.89, 2.13 to 0.97, 2.23 to 2.01, 1.27 to 0.68, 0.80 to 0.70, 0.537 to 0.590, 81.76 to 80.98, 36.16 to 37.08, 46.96 to 44.27, respectively. DAS28-CRP, and all of its components, and EGA demonstrated significant decrease, although PS-VAS showed decrease yet demonstrated no significance, while HAQ-DI showed increase with no statistical significance. dSHS and dBE demonstrated significant less at AFT than at BEF, while no significance for dJSN yet slightly increased in the AFT, even no significant difference demonstrated for absolute values (table 1).

Abstract AB0443 – Table 1. Change of each parameters and statistical significance. BMD, bone mineral density; % YAM, percentage of young adult mean value; BEF, before administration of denosumab; AFT, first value after denosumab was administered; S.S., statistical significance; LS, average value of lumbar spine from L1 to L4; FN, femoral neck; GT, greater trochanter; DAS28-CRP, 28-joints disease activity score with C-reactive protein; TJC, tenderness joint count; SJC, swollen joint count; PGA, patient's global assessment; CRP, C-reactive protein; EGA, evaluator's global assessment; PS-VAS, pain score with visual analogue scale; HAQ-DI, Health Assessment Questionnaire Disability Index; SHS, Sharp/van der Heijde Score; JSN, joint space narrowing score; BE, bone erosion score; n. s., not significant; *, AFT is statistically significantly smaller than BEF within 1%; §, BEF is statistically significantly larger than AFT within 1%.

| BMD (%YAM) | BEF | AFT | S.S. |
|------------|-------------|-------------|------|
| LS | 74.03±15.74 | 77.32±15.79 | * |
| FN | 69.79±11.65 | 69.63±11.93 | n.s. |
| GT | 71.99±13.82 | 74.27±13.28 | * |
| TRACP-5b | 489.3±214.4 | 255.3±133.6 | § |
| DAS28-CRP | 2.12±0.91 | 1.86±0.72 | * |
| TJC | 1.32±2.20 | 0.89±1.99 | * |
| SJC | 2.13±3.54 | 0.97±1.85 | * |
| PGA | 2.23±2.30 | 2.01±1.88 | * |
| CRP | 0.80±1.55 | 0.70±1.36 | n.s. |
| EGA | 1.27±1.64 | 0.68±1.07 | * |
| PS-VAS | 28.34±23.32 | 27.07±21.65 | n.s. |
| HAQ-DI | 0.537±0.611 | 0.590±0.648 | § |
| SHS | 81.76±89.36 | 80.98±89.65 | n.s. |
| JSN | 36.16±37.76 | 37.08±38.57 | § |
| BE | 45.96±53.08 | 44.27±52.18 | * |

Conclusions: The effect of dMAB on RA is suggested suppression of dBE, BMD increase in LS and GT, improvement of DAS28-CRP, and may have decrease of PS-VAS.

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AB0444 DESCRIPTION IN REAL-WORLD OF THE EFFICACY AFTER SWITCHING FROM INTRAVENOUS TO SUBCUTANEOUS ADMINISTRATION OF TOCILIZUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS. THE ROSWITCH STUDY

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Background: It has been proven, in a pivotal RCT, that SC tocilizumab (TCZ) was non-inferior to IV TCZ.¹ However the switch from IV to SC TCZ has not been evaluated to date in a large real-world study.

Objectives: The main objective was to assess the maintenance of efficacy of SC TCZ 6 months (M6) after switching from IV to SC formulation in patients (pts) with rheumatoid arthritis (RA) in real-world. Secondary objectives were: characteristics of pts and RA, efficacy of TCZ at M12, TCZ retention rates at M6 and M12 for Switch (IV-SC) and No-Switch pts (IV-IV), predictive factors of switching.

Methods: We analysed all RA pts of the shared medical file "RIC Nord de France" with ≥1 DAS 3 months before inclusion, treated with TCZ, switching or not from IV to SC TCZ, between April 30 2015 and January 15 2016. The primary efficacy endpoint was the % of pts remaining in their DAS28-ESR category remission/LDA or moving to an inferior DAS category at M6. Various sensibility analyses were realised on the primary criterion of which a propensity score (IPTW).

Results: From the 314 included pts, 30% switched from IV to SC TCZ. At baseline, 77.7% were females, mean BMI was 27.5±6.4, mean RA duration was 14.9 ±9.2 years. Mean IV TCZ duration before inclusion was 35.0±23.1 months in Switch and 26.8±22.1 months in No-Switch pts. Mean DAS28 were 2.1±1.1 in Switch and 2.9±1.6 in No-Switch pts. 81.9% and 59.5% of the pts were in DAS28 remission/LDA, 18.1% and 28.6% in MDA, 0% and 11.8% in HAD in Switch and