- [2] Rogers, G. B. Germs and joints: the contribution of the human microbiome to rheumatoid arthritis. *Nat. Med.* **21**, 839–841, doi:10.1038/nm.3916 (2015).
- [3] Holers, V. M. *et al.* Rheumatoid arthritis and the mucosal origins hypothesis: protection turns to destruction. *Nature reviews. Rheumatology*, doi:10.1038/s41584-018-0070-0 (2018).

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OP0017

THERAPEUTIC DRUG MONITORING COMPARED TO STANDARD TREATMENT OF PATIENTS STARTING INFLIXIMAB THERAPY: RESULTS FROM A MULTICENTRE RANDOMISED TRIAL OF 400 PATIENTS

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Background: A lack or loss of response to TNF α inhibitors (TNFi) has been associated with low serum drug levels and formation of anti-drug antibodies (ADAb). Therapeutic drug monitoring (TDM), an individualised treatment strategy based on regular assessments of serum drug levels, has been suggested to optimise efficacy of TNFi. It is still unclear if TDM improves clinical outcomes, and the value of TDM has recently been included in the research agenda across different specialities. This first randomised controlled trial on the effectiveness of TDM in a range of immune mediated inflammatory diseases including rheumatic diseases, the NORwegian DRUG Monitoring trial part A (NOR-DRUM (A)) focus on the induction period of infliximab (INX) treatment.

Objectives: To assess if TDM is superior to standard treatment in order to achieve remission in patients starting INX.

Methods: In the investigator-initiated, randomised, open-label, multicentre NOR-DRUM (A) study, adult patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), spondyloarthritis (SpA), ulcerative colitis (UC), Crohn's disease (CD) and psoriasis (Ps) starting INX therapy were randomly assigned to administration of INX according to a treatment strategy based on TDM (TDM arm) or to standard administration of INX without TDM (control arm). Study visits were conducted at each infusion. The primary endpoint was remission at week 30. In the TDM arm, the dose and interval were adjusted according to INX trough levels to reach the therapeutic range (Figure 1). If the patient developed significant levels of ADAb, INX was terminated. To guide the investigators, the TDM strategy was integrated in an interactive eCRF. The primary endpoint was analysed by mixed effect logistic regression in the full analyses set (FAS), adjusting for diagnoses. Infections and infusion reactions were specified as adverse events (AEs) of special interest. Clinical trial.gov: NCT03074656

Results: We enrolled 411 patients at 21 study centres between January 2017 and December 2018. 398 patients (RA 80, PsA 42, SpA 117, UC 80, CD 57, Ps 22) received the allocated strategy and were included in the FAS population. Demographic and baseline characteristics were comparable in both arms. TDM was not found to be superior to standard treatment with regard to the primary outcome. Remission at week 30 was reached in 100 (53%) and 106 (54%) of the patients in the TDM and control arm, respectively (adjusted difference, 1.5%; 95% confidence interval (CI), -8.2 to 11.1, $p=0.78$) (Figure 2). Consistent results were shown for all the secondary endpoints (Figure 3) and in the sensitivity analyses. Twenty patients (10%) in the TDM arm and 30 patients (15%) in the control arm developed significant levels of ADAb. The number of adverse events (AE) was similar in both groups, however infusion reactions were less frequent (5 patients (2.5%) vs 16 patients (8.0%)) in the TDM arm (difference 5.5% (95% CI 1.1, 9.8%)).

Conclusion: NOR-DRUM (A) is the first randomised trial to address effectiveness of TDM in the induction period of TNFi treatment, and the first trial to address TDM in rheumatic diseases. In this study, TDM was not superior to standard treatment in order to achieve remission. Although improved safety is indicated by a reduction in infusion reactions, implementation of TDM as a general strategy in the induction period of INX is not supported by the NOR-DRUM (A) study.

Figure 1 Treatment strategy in the TDM arm

Figure 2. Difference in remission rate, overall and by disease

Figure 3. Generic (A-F) and disease specific (G-L) composite measures over study period.

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LB0001

EFFICACY AND SAFETY OF UPADACITINIB VERSUS PLACEBO AND ADALIMUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AND INADEQUATE RESPONSE TO NON-BIOLOGIC DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS (SELECT-PSA-1): A DOUBLE-BLIND, RANDOMIZED CONTROLLED PHASE 3 TRIAL

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Conclusion: In this non-bDMARD-IR PsA population, treatment with UPA15/30 demonstrated improvement in musculoskeletal symptoms, psoriasis, physical function, pain, and fatigue and inhibited radiographic progression; improvements were observed by Wk 2. At Wk 12, UPA15/30 were non-inferior to ADA for ACR20, with superiority demonstrated for UPA30. Greater percentages of UPA vs PBO pts achieved stringent measures of disease control (MDA, ACR50/70, sIGA 0/1). No new safety signals were identified compared with the safety profile observed in RA.

[illegible]

FIGO, placebo; UPA, upadacitinib; ADA, adalimumab; QO, once daily; EOW, every other week; NMIC, non-melanoma skin cancer; MACE, major adverse cardiovascular events; VTE, venous thromboembolic events

Biological DMARDs in RA I.

A MULTICENTER RANDOMIZED STUDY IN EARLY RHEUMATOID ARTHRITIS TO COMPARE ACTIVE CONVENTIONAL THERAPY VERSUS THREE BIOLOGICAL TREATMENTS: 24 WEEK EFFICACY RESULTS OF THE NORD-STAR TRIAL

Results: 812 pts were randomized. Age was 54.3 ± 14.7 yrs (mean $\pm$ SD), 31.2% were male, DAS28 5.0 ± 1.1 , 74.9% were RF and 81.9% ACPA positive. Fig 1 shows the adjusted CDAI remission rates over time with 95% CI. Table shows crude remission and response rates and absolute differences in adjusted