Background: TNF-inhibitors have improved treatment of Crohn's disease (CD), ulcerative colitis (UC), spondyloarthritis (SpA), rheumatoid arthritis (RA), psoriatic arthritis (PsA) and chronic plaque psoriasis (Ps). The aim of the Nor-Switch study was to examine switching from originator to biosimilar infliximab regarding efficacy, safety and immunogenicity.
Methods: The study was designed as a 52-week randomised, double-blind, non-inferiority trial. Patients with a diagnosis of CD, UC, SpA, RA, PsA or Ps on stable maintenance treatment with the originator infliximab (Remicade®, INX) were randomized 1:1 to either continued INX or switch to biosimilar infliximab (Remsima®, CT-P13). The primary endpoint was disease worsening according to disease activity indices during follow-up.
Results: In total, 481 patients at 40 Norwegian study centres were randomised, with 202/206 patients in the INX/CT-P13 arms (Per Protocol Set). There were 129 (32%) and 75 (18%) patients with CD and UC. Overall disease worsening occurred in 26.2% and 29.6% of patients in the INX and CT-P13 arms, respectively, and the 95% confidence interval (CI) of the adjusted difference was within the pre-specified non-inferiority margin (–4.4; 95% CI –12.7, 3.9%). In CD, disease worsening occurred in 21.2% and 36.5% (CI –29.3 to 0.7%) and in UC 9.1% and 9% (CI –15.2, 10.0%). The CI for CD was close to non-inferiority for CT-P13, but disease specific analyses were pre-specified as exploratory and NOR-SWITCH was not powered for demonstrating non-inferiority in the single diagnoses.
The baseline characteristics in CD and UC showed no difference between treatment arms regarding previous biologic therapy, use of immunosuppressives, trough drug levels, disease duration, distribution, behaviour and activity (Harvey-Bradshaw Index (HBI) and Partial Mayo Score (PMS)), bowel surgery, smoking, CRP, fecal calprotectin, and EQ-5D.
Changes in parameters from baseline to study end showed similarity between arms (adjusted difference, (95% CI)) in CD and UC, respectively, regarding CRP (–0.07 (–0.17, 0.04) and –0.04 (–0.18, 0.10)), fecal calprotectin (–0.08 (–0.27, 0.10) and 0.21 (–0.03, 0.44)), HBI (–0.41 (–1.14, 0.33)), PMS (0.14 (–0.30, 0.59)), HBI and PMS remission. Changes in Patient's and Phycician's global assessment of disease activity showed some larger improvement in the INX compared to the CT-P13 arm in the CD group (–0.65 (–1.22, –0.07) and –0.42 (–0.85, 0.001)). Comparable results were also seen for through serum levels, presence of anti-drug antibodies and reported adverse events.
Conclusions: Explorative subgroup analyses of CD and UC in the Nor-Switch study showed similarity between patients treated with INX and CT-P13 with regard to efficacy, safety and immunogenicity.

DOP063
Serial tuberculin skin test improves the detection of latent tuberculosis infection in inflammatory bowel disease patients

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Background: Despite preventive action, active tuberculosis (TB) still occurs in patients on anti-TNF therapy. Steroids and/or immunosuppressants markedly reduce sensitivity of tuberculin skin test (TST) performed before anti-TNF therapy. The risk of conversion of serial TST in inflammatory bowel disease (IBD) patients whose initial 2-step TST was negative is not well known. This study aimed to determine the likelihood of detecting latent TB infection by the positive conversion of annual TST in IBD patients.
Methods: This prospective multicentre controlled study included consecutive IBD patients on anti-TNF therapy and a control cohort of IBD patients not receiving anti-TNF therapy. All patients with a negative initial 2-step TST had a second test one year later. We evaluated the rate and predictors of TST conversion (including change in number of immunosuppressive drugs [steroids and/or immunosuppressants and/or anti-TNF]). We recorded management of cases of TST conversion and occurrence of active TB during follow-up.
Results: The 412 patients enrolled (mean age 44 years, 54% male) included 192 patients (47%) on anti-TNF and 220 controls (53%). Thirty-five patients (8.5%, 95% confidence interval [CI]: 5.7–11.3) had a positive conversion in the annual TST (median TST induration 13 mm, range 5–20]). Eleven of 192 anti-TNF patients (5.8%, 95% CI 2.2–9.3) vs. 24 of 220 controls (10.9%, 95% CI 6.6–15.2) had TST conversion (p=0.037). In multivariate analysis patients receiving anti-TNF therapy had a lower rate of TST conversion (odds ratio [OR] 0.36, 95% CI 0.15–0.83, p=0.017). Conversely, smokers had a higher rate of TST conversion (OR 3.62, 95% CI 1.66–7.88, p=0.001). The likelihood of conversion according to changes in immunosuppressive therapy from baseline was 16.6%, 7.9%, 7.3%, 4.5% and 0% for patients with 1 drug less, same number of drugs or 1, 2 or 3 drugs more, respectively (p=0.016). All 11 anti-TNF cohort patients with an annual positive TST received treatment for latent TB infection and continued with anti-TNF therapy. Eleven of 24 control patients with TST conversion received preventive therapy. No patient developed active TB after 607 and 676 patient-years of follow-up of anti-TNF exposed and control patients, respectively.
Conclusions: Patients with IBD were at high risk of conversion in the annual TST after an initial negative 2-step TST. Anti-TNF therapy reduced the likelihood of annual TST conversion. Although the exact significance of these positive conversions is not well known, annual TST seems to be advisable as baseline false negative responses to latent TB infection or new TB contacts are possible in IBD patients receiving long-term anti-TNF therapy, especially in countries with a moderate to high prevalence of TB.