Objectives: We hypothesised that if IMB is indeed an RA-feature, then (1) at diagnosis its presence associates with other measures of local inflammation (synovitis, tenosynovitis and osteitis) and (2) it responds to DMARD therapy similarly as these other local inflammatory measures. These hypotheses were tested in a comprehensive MRI-study.

Methods: 157 consecutive early RA patients underwent unilateral contrast-enhanced 1.5T MRI of the forefoot at diagnosis. MRIs were evaluated for presence of IMB and for synovitis, tenosynovitis and osteitis in line with the RA MRI scoring system (summed as RAMRIS-inflammation). MRIs at 4, 12 and 24 months were evaluated for presence and size of IMB-lesions in patients who had IMB at baseline and received early DMARD-therapy. Logistic regression was used for analyses at patient-level; generalised estimating equations were used for bursa-level analyses. Stratification for ACPA was performed.

Results: 69% of RA patients had ≥ 1 IMB. In multivariable analyses on bursa-level, presence of IMB was independently associated with local presence of synovitis and tenosynovitis (OR 1.69 (95%CI 1.12–2.57) and 2.83 (1.80–4.44), respectively), but not with osteitis. On patient-level, presence of IMB was most strongly associated with tenosynovitis (OR 2.92 (1.62–5.24)). During treatment with DMARDs, the average size of IMB-lesions decreased (Figure 1). This decrease was associated with decrease in RAMRIS-inflammation scores; most strongly with a decrease in synovitis but not in osteitis. Within ACPA-positive and ACPA-negative RA similar results were obtained.

Conclusion: IMB particularly accompanies inflammation of the synovial lining of joints and tendon-sheaths, both regarding simultaneous occurrence at diagnosis and simultaneous treatment-response. These findings suggest that IMB represents juxta-articular synovial inflammation and indeed is a hallmark of early RA.

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POS0022

PHARMACOVIGILANCE PREGNANCY DATA IN A LARGE POPULATION OF PATIENTS WITH CHRONIC INFLAMMATORY DISEASE EXPOSED TO CERTOLIZUMAB PEGOL: PREGNANCY OUTCOMES AND CONFOUNDERS

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Background: Chronic inflammatory diseases (CID) in women of reproductive age are increasingly being treated with tumour necrosis factor inhibitors (TNFi), in line with recent guidelines.¹ However, data on TNFi-exposed pregnancy outcomes are still limited. Certolizumab pegol (CZP), a PEGylated, Fc-free TNFi, has no/minimal placental transfer from mother to infant during the third trimester.²

Objectives: To assess pregnancy outcomes from the UCB Pharmacovigilance safety database from over 1,300 prospectively reported pregnancies with maternal CZP exposure.

Methods: Details of CZP-exposed pregnancies from the UCB Pharmacovigilance safety database were reviewed up to November 1, 2020. Analysis was limited to prospectively reported cases with known pregnancy outcomes to avoid potential reporting bias. Confounders (specific CID, non-biologic medications and maternal infection) were evaluated using a multivariate stepwise regression model; results from the confounders analysis are reported as odds ratios (OR) with 95% confidence intervals (CI). Patients with missing information about presence or absence of confounders were excluded from the model.

Results: 1,392 prospective pregnancies (1,425 fetuses) with maternal CZP exposure and known outcomes were reported (Figure 1). Mean (SD) maternal age was 31.9 (5.1) years. Of these, 1,021/1,392 (73.3%) pregnancies had at least first-trimester CZP exposure and 547/1,392 (39.3%) were exposed during all trimesters. Overall, there were 1,259/1,425 (88.4%) live births, 150/1,425 (10.5%) abortions (miscarriages and terminations), 11/1,425 (0.8%) stillbirths, and 5/1,425 (0.4%) ectopic pregnancies. Congenital malformations were reported in 35/1,425 fetuses (2.5%) and in 30/1,259 live-born infants (2.4%); 26 (2.1%) congenital malformations were major according to the Metropolitan Atlanta Congenital Defects Program criteria. There was no pattern of specific congenital malformations. Preterm births occurred in 124/1,259 (9.8%) live births, and 101/1,259 (8.0%) of infants had low birth weight (<2.5 kg). In the confounders analysis, reported corticosteroid use was independently

associated with increased odds of preterm birth (OR [95% CI]: 2.1 [1.3–3.4]; $p < 0.005$) and low birth weight (OR [95% CI]: 1.7 [1.0–2.9]; $p < 0.05$), but decreased odds of abortion (OR [95% CI]: 0.5 [0.3–0.9]; $p < 0.05$). Reported NSAID use was associated with increased odds of abortion (OR [95% CI]: 2.2 [1.2–4.0]; $p < 0.05$), as was methotrexate/leflunomide use (OR [95% CI]: 3.2 [1.7–6.2]; $p < 0.0005$). Maternal infections were associated with increased odds of preterm birth (OR [95% CI]: 1.9 [1.1–3.5]; $p < 0.05$). Finally, there was an association between a diagnosis of Crohn's disease and odds of abortion (OR [95% CI]: 2.5 [1.5–4.1]; $p = 0.0005$), and between rheumatoid arthritis and low birth weight (OR [95% CI]: 1.9 [1.1–3.3]; $p < 0.05$).

Conclusion: This prospective analysis, including more than 1,000 pregnancies with CZP exposure in at least the first trimester, represents one of the largest cohorts of pregnancies with known outcomes in patients with CID. Our data confirm the impact of specific CID, concomitant drugs or comorbidities on pregnancy outcomes. In particular, additional use of corticosteroids was highlighted as a risk factor for preterm birth and low birth weight in our cohort of CZP-treated patients. No increase in adverse pregnancy outcomes or specific congenital malformations was observed in CZP-exposed pregnancies, compared to the general population,^{3,4} which offers further reassurance for women of childbearing age considering CZP treatment.

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Figure. Reports of pregnancies exposed to CZP identified in the UCB Pharmacovigilance safety database

Some patients may have had multiple indications for CZP treatment. axSpA: axial spondyloarthritis; CZP: certolizumab pegol; PsA: psoriatic arthritis; RA: rheumatoid arthritis.

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POS0023

RACIAL/ETHNIC AND REGIONAL DIFFERENCES IN MULTIMORBIDITY BETWEEN PATIENTS WITH RHEUMATOID ARTHRITIS AND COMPARATORS IN A LARGE NATIONWIDE US STUDY

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