# Disease Activity and Outcome in Pregnancies of Patients with SpA – Data from the German Pregnancy Register RHEKISS

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## Conclusions

- Discontinuation of bDMARDs after conception is associated with increased disease activity and a higher risk of flares during pregnancy and after birth.
- Women exposed to bDMARDs at conception are not at higher risk for adverse pregnancy outcomes compared to those without bDMARD exposure.

## Objectives

The aim of this study was to compare disease activity during pregnancy in patients with or without exposure to a biological DMARD (bDMARD) at conception and during pregnancy and to assess pregnancy outcomes stratified by bDMARD exposure.

## Patients & Methods

RHEKISS is a prospective longitudinal cohort study in Germany including women with a confirmed diagnose of inflammatory rheumatic disease either at child wish or during pregnancy. Pregnant women are eligible to be enrolled until the 20th week of gestation regardless of drug treatment. During observation, information on treatment, disease and pregnancy course, and outcome are collected from rheumatologists and patients.

For this analysis, pregnancies of patients with **SpA** and a reported outcome until June 8th 2020 were selected and stratified into the following three groups according to their exposure to bDMARDs:

**Group A**: no bDMARD exposure at conception

**Group B**: bDMARD at conception but not during pregnancy

**Group C**: bDMARD exposure at conception and continuously during pregnancy

## Results

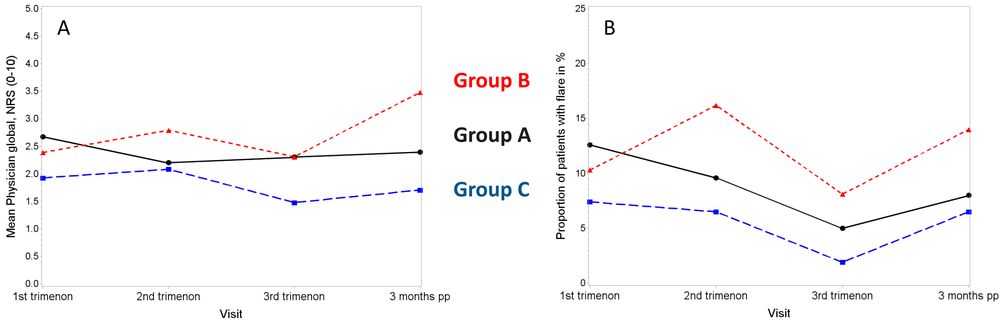
In 129 women with SpA, **140 pregnancies** were reported with known pregnancy outcome. Of those, 74 (53%) occurred in **group A**, 38 (27%) in **group B** and 28 (20%) in **group C**.

## Results

***Table 1:*** *Baseline characteristics in pregnancies*

| | Group A n=74 | Group B n=38 | Group C n=28 | Total n=140 |
|---|---|---|---|---|
| Singleton, n (%)<br>Twin<br>Triple | 72 (98)<br>1 (1)<br>1 (1) | 37 (97)<br>1 (3)<br>0 | 28 (100)<br>0<br>0 | 137 (98)<br>2 (1)<br>1 (1) |
| New-York criteria fulfilled, n (%) | 21 (33) | 17 (49) | 10 (48) | 48 (40) |
| Disease duration (years), mean (SD) | 6.4 (5.9) | 7 (4.1) | 5.8 (4) | 6.4 (5.1) |
| Age at beginning of pregnancy, mean (SD) | 33.4 (4.9) | 32.3 (4) | 31.6 (3.4) | 32.7 (4.4) |
| Severity of illness, n (%)<br>asymptomatic<br>mild<br>moderate<br>severe | <br>4 (6)<br>31 (48)<br>24 (38)<br>5 (8) | <br>0<br>6 (17)<br>21 (60)<br>8 (23) | <br>3 (14)<br>4 (19)<br>14 (67)<br>0 | <br>7 (6)<br>41 (34)<br>59 (49)<br>13 (11) |
| HLA-B27 positive, n (%) | 41 (62) | 24 (80) | 15 (75) | 80 (69) |
| CRP in mg/l, mean (SD) | 6.6 (8.2) | 5.4 (8.2) | 5.2 (4.9) | 6 (7.6) |
| CRP >5mg/l, n (%) | 25 (41) | 9 (30) | 8 (35) | 42 (37) |

***Figure 1:*** *Mean course of physicians' assessed global disease activity (A) and proportion of flares (B) at three visits during pregnancy and 3 months post partum*




Women in **group B** received the following bDMARDs at conception: 29% certolizumab, 29% adalimumab, 16% infliximab, 13% etanercept, 5% golimumab, and one woman each (=3%) secukinumab, ustekinumab and ixekizumab.

In **group C** 78% of the women were exposed to certolizumab, 11% etanercept, and 11% to adalimumab.

***Table 2:*** *Pregnancy outcomes of singleton pregnancies*

| | Group A n=72 | Group B n=37 | Group C n=28 | Total n=137 |
|---|---|---|---|---|
| Live birth, n (%) | 69 (96) | 35 (95) | 26 (93) | 130 (95) |
| Gestational week at birth, mean (SD) | 39.4 (1.7) | 38.4 (2.8) | 39.8 (2.8) | 39.2 (2.4) |
| < week 37, n (%)<br>≥ week 37, n (%) | 2 (6)<br>32 (94) | 2 (11)<br>16 (89) | 1 (5)<br>19 (95) | 5 (7)<br>67 (93) |
| Delivery mode, n (%)<br>spontaneous<br>Operativ-vaginal<br>sectio | <br>40 (70)<br>1 (2)<br>16 (28) | <br>18 (56)<br>0<br>14 (44) | <br>9 (47)<br>0<br>10 (53) | <br>67 (62)<br>1 (1)<br>40 (37) |
| abortion, n<br>termination, n | 2*<br>1** | 2***<br>0 | 2***<br>0 | 6<br>1 |

* Two abortions in the same patient in different pregnancies, in gestational week 10 and 7

** Elective termination at gestational week 22 due to suspected malformation

*** Abortion in group B at gestational week 10 and 16, in group C at gestational week 9 and 11

All babies of the twin pregnancies were born healthy. In one triple pregnancy two babies aborted in week 13 and one baby was born alive.

Complications occured comparable in all groups. In total, bleedings were reported in 11 (8%) pregnancies, gestational diabetes in 8 (6%), premature labor in 8 (6%) and arterial hypertension in 2 (2%) pregnancies. One (0.7%) pre-eclampsia was reported in group B, one (0.7%) HELLP syndrome occured in group A.

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