AIM: Few studies have been conducted on the risks of exposure to anti-TNFs before or during pregnancy, therefore current recommendations are based on limited evidence. The aim of this study was to assess the impact of treatments with anti-TNFs on foetal development and pregnancy outcome.

PATIENTS AND METHODS: Pregnancies occurring during anti-TNF treatment or less than 3 months after withdrawal of it in patients with IBD followed in GETAID centres, were recorded from January 2009 and are planned to be recorded until December 2010. Dosage and duration of exposure to anti-TNFs and associated treatments were recorded. Disease activity as well as maternal-foetal, obstetrical and neonatal complications were ascertained.

RESULTS: Until November 2010, 127 pregnancies were recorded in 120 patients, of whom 85 (65CD, 18UC, 2 IC) were fully documented in 81 patients (median age 28 years). Among them, 6/85 (7%) miscarriages occurred, 49/85 (58%) pregnancies were carried to term and resulted in 47 live births, 30/85 (35%) pregnancies are ongoing. At conception, 23/85 (27%) patients were in relapse and 62/85 (73%) in clinical remission. Thirteen/62 (21%) patients in remission at the time of conception experienced flares during pregnancy. The anti-TNFs used were infliximab, adalimumab and certolizumab in 63% (54/85), 34% (29/85) and 2% (2/85). Immunosuppressants were given in association in 16% (14/85) of cases (AZA=11, 6-MP=3). The median duration of anti-TNF treatment at the time of conception was 357 days. Of the 49 completed pregnancies, anti-TNFs were preventively interrupted in 31/49 (63%) patients at the end of 6th gestational month and pursued until delivery in 14/49 (29%) patients. Completed pregnancies were uneventful in 33/49 (67%) cases and were associated with adverse events in 16/49 (32%) cases: 8 (17%) premature deliveries (<37 GW) of children born alive, 3 (6%) deaths (2 deaths in utero, 1 extreme prematurity), 1 HELLP syndrome, 2 gestational cholestasis, 1 maternal infection, 1 colectomy for severe UC. In the group of complicated pregnancies, 5/16 (31%) patients were in relapse at the time of conception vs. 27% among the normal pregnancies group. Among the 46 infants alive, 7 (15%) presented 10 neonatal complications, namely 6 (13%) foetal hypotrophy (birth weight <2500g), 3 respiratory distress syndromes and 1 foetal infection. Median birth weight was 3.1kg (1.9-3.78) and median birth size was 49cm (43-52).

CONCLUSION: These interim results suggest that one third of pregnancies exposed to anti-TNF agents are complicated. These data do not seem to differ from those reported in the IBD population, suggesting an absence of excess risk linked to anti-TNF therapy. Based on the number of patients currently collected, the results for at least 125 births under anti-TNF will be available by May 2011.