CONCEIVE

Dear colleagues,

Very few data are available regarding **pregnancy outcomes in female patients with inflammatory bowel disease treated with vedolizumab**. Given that patients typically present at an age which falls within child-bearing potential, it is important to provide information and advice to female patients and their partners about conception and the potential risks for both the mother and the (unborn) child.

During the last ECCO congress, two original abstracts were presented regarding the outcome of pregnancies in patients treated with vedolizumab. In a Belgian cohort, 24 pregnancies under vedolizumab were reported (Moens A *et al*, ECCO 2018, OP032). Complications were observed in 39% of mothers and in 35% of infants. Due to the low number of reported pregnancies and the fact that no control group was included, no firm conclusions could be drawn. In a cohort of Jerusalem, 20 pregnancies under vedolizumab were compared with 81 pregnancies under anti-TNF and 230 pregnancies under no biological therapy (Bar-Gil Shitrit A *et al*, ECCO 2018, P279). Birth weights and Apgar scores were comparable between groups. Thirteen out of twenty pregnancies under vedolizumab lead to live birth, including two preterm deliveries. Six early miscarriages were observed, as well as one late miscarriage. **Expanding these study initiatives to a European level would certainly provide more data on the safety of vedolizumab in pregnancy and offspring.**

With this email, the University Hospitals of Leuven (Leuven, Belgium), the Erasmus MC (Rotterdam, The Netherlands) and the Shaare Zedek Medical Center (Jerusalem, Israel), would like to ask different European research groups as well as individual IBD centers to **collaborate on this topic in a retrospective, multi-center cohort study**. Each participating center will be requested to collect data on the outcome of pregnancies in patients treated with vedolizumab. As a control group, we plan to include two cohorts of patients treated with other biologicals or no biological therapy during pregnancy (Erasmus MC, Rotterdam, The Netherlands and Shaare Zedek Medical Center, Jerusalem, Israel). The study protocol (see attachment) has been reviewed extensively by the Clinical Committee (ClinCom) of ECCO and is supported by ECCO. The study with unique code S60985 was also approved by the Ethical Committee of the University Hospitals of Leuven (Leuven, Belgium).

Who can collaborate?

- IBD centers which maintain a **prospective list of patients treated with vedolizumab** (to avoid any bias through missed cases)
- IBD centers who are willing to provide data on all pregnancies under vedolizumab with an **(expected date of) delivery before July 1th 2018** (allowing at least 3 months of follow-up in the offspring by the ECCO deadline, and 6 months of follow-up by the submission of the full manuscript)
- IBD centers who are willing to verify themselves if approval by their local **ethical committee** and **informed consent** of the mother (and the father) is mandatory in their jurisdiction for a retrospective study which does not only include data of the mother but also from the (unborn) child. If so, the IBD center will be responsible for the submission to the local ethical committee as well as collection of the informed consent forms (English template in attachment). As mentioned, the study was already approved by the Ethical Committee of UZ Leuven (S60985).
- IBD centers who are willing to fill out completely and correctly a **4 pages clinical research form** by October 1th 2018. The clinical research form will include data on diagnosis, disease activity and medical therapy prior, during and after delivery, pregnancy outcomes, vaccination status of the children, occurrence of severe infections and cancers in the offspring.
- IBD centers who are willing to do everything to **avoid missing data** as much as possible by contacting patients, colleague gastroenterologists, general practitioners and pediatricians.

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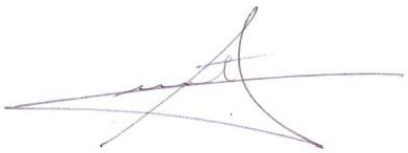
If you are interested in collaboration to this study, **please contact marc.ferrante@uzleuven.be by July 1th 2018**. Inform us, if you need ethical approval and informed consent of each patient, and when you will expect this. **Please also forward this email to other IBD centers in your country.**

We will aim for the submission of an abstract for ECCO 2019 and a full manuscript shortly thereafter. The **publication list** will take into account the number of patients included in the study. Most likely, not all participants will be included in the main author's list, but everyone will be mentioned as collaborator and therefore traceable through a PubMed search.

Of note, IBD centers who collaborate to this multi-center cohort study are allowed to publish their own data independently as well. However, joint forces will lead to a manuscript with a higher impact.

This initiative was already discussed at the ECCO National Study groups meeting and received a lot of positive feedback. Therefore, **we truly hope that this retrospective study will become a success and might lead to an intense collaboration maybe including a prospective database on pregnancy outcomes.**

Looking forward,



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