

Dear ECCO National Representatives,  
Dear IBD National Study Group Representatives,  
Dear colleagues,

Very few data are available regarding fertility and achieved pregnancies in patients undergoing surgery for inflammatory bowel diseases (IBD), such as Crohn's Disease (CD) and Ulcerative Colitis (UC). Abdominal surgery, especially pelvic surgery, is associated with reduced fertility. Previous studies with limited and low-quality patient numbers have found reduced infertility rates with a minimally invasive approach, but the issue is controversial.

The management of pregnancy and childbirth in patients with previous abdominal surgery for CD or UC are a topic of debate. In particular, little is known about the outcomes and need of seek for treatments to achieve successful termination of the gestation. Lastly, the ideal approach to pregnant patients with IBD previously submitted to abdominal surgery is debated. Of note, the patient's perspective has not been investigated in detail.

This is very relevant, if considering that IBD affect patients at young age, thereby potentially causing long-term sequelae if surgery is needed. Also, repeated surgery may be needed in a significant proportion of CD patients. Very commonly, surgery for IBD is aimed to improve quality of life. Ability to conceive and the possibility of creating a family are important factors to be considered when deciding which treatment should be offered to each specific patient.

The Fertile-IBD study aims at assessing how surgery impacted the ability to become pregnant and the outcomes of pregnancy in this population. The protocol was developed with the participation of patient representatives, to confirm that relevant outcomes and co-variables are included

The eventual aim is to produce rapidly further evidence on a topic that has been often neglected, offering perspectives for future studies and useful information that might need to be discussed with patients at the time of deciding the ideal their treatment, resulting in an empowered shared decision making.

Patient integration in the development of the protocol and at an early stage of the project will ensure that the findings are relevant to patients, and a lay-summary report is planned to inform the involved stakeholders and the public.

Expanding this study to a European level would certainly provide more data on fertility and achieved pregnancies in patients undergoing surgery for inflammatory bowel diseases.

With this email, the FERTILE-IBD group 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 female patients with a confirmed diagnosis of CD or UC that underwent surgery before the age of 36 years from 2000 to 2022. For the non-surgical group, all patients who received treatment for CD or UC from 2000 to 2022 will have to be included. The deadline for the data collection period will be October 30, 2023.

The amended study protocol (see attachment) has been reviewed extensively by the Clinical Committee (ClinCom) of ECCO. The initial study with unique code **NCT04663971** was also approved by the Ethical Committee of the University of Campania Vanvitelli (Naples, Italy)

## **Who can collaborate?**

Participation is open to all general surgery/colorectal surgery centers with a medium-high IBD incidence (at least 50 patients included in the study period) which wish to contribute to the study, provided that Ethical Committee approval is obtained, according to local regulation.

Local teams may include up to 4 individuals (3 collaborators and 1 data validator) who will be listed as authors/collaborators on scientific publications resulting from the study. Each team will have a local leader.

**If you are interested in collaboration to this study, please contact [fertility.ibd@gmail.com](mailto:fertility.ibd@gmail.com) by March 31, 2023.**

We will aim for the submission of an abstract for ECCO 2024 and a full manuscript shortly thereafter. The publication list of authors will take into account the number of patients included in the study, but everyone will be mentioned as collaborator and therefore traceable through a PubMed search.

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 study will become a success and might lead to an intense collaboration.

Looking forward to welcoming you onboard,

Prof. Gianluca Pellino  
Dr. Alice Gori