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

**Hemorrhoidal disease** (HD) is a prevalent condition, often presenting with symptoms such as bleeding, anal swelling, prolapse, and pain. When it occurs in patients with IBD, including Crohn's disease (CD) and ulcerative colitis (UC), the clinical management becomes more complex and nuanced. Our previous systematic review highlighted the need for a comprehensive understanding of surgical treatments for HD in this unique population, given the **significant morbidity** associated with HD surgery, particularly in patients with CD.

The **HEAD-IBD-II** study aims to address the gaps identified in existing literature by conducting an **international, prospective cohort investigation**. Our primary goal is to assess the safety and effectiveness of surgical treatments for HD in patients with IBD. We aim to collect detailed data on surgical practices, clinical recovery, and long-term outcomes to guide future treatment guidelines and improve clinical decision-making.

The study is currently receiving approval by the local Ethical Committee of the Coordinating Centre.

## Inclusion and Exclusion Criteria

- Inclusion Criteria:
  - Patients aged 18 years and above
  - Patients with a current diagnosis of CD or UC undergoing surgery for HD
- Exclusion Criteria:
  - Previous surgery for HD other than office-based treatments (i.e., sclerotherapy and/or rubber band ligation)
  - Patients with active perianal disease at the time of surgical intervention

## Who can collaborate?

We invite IBD centres across Europe to participate in this study. Collaboration is open to centres that:

- Have the capability to retrieve data on IBD patients undergoing surgery for HD.
- Are willing to fill out an electronic clinical research form (eCRF) through REDCap® software for all included patients.
- Obtain approval by their local ethical committee and informed consent of the patient for this study.

## How to Participate

If your centre is interested in collaborating on this study, please contact Ugo Grossi at <u>ugo.grossi@unipd.it</u> by **September 20, 2024**.

We are enthusiastic about the potential of this study to significantly advance our understanding of surgical management for HD in IBD patients and hope for widespread participation from the European IBD community. We truly hope that this prospective study will enhance collaborations across our community.

Sincerely,

Dr. Ugo Grossi

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