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

It is known that up to 25% of patients with ulcerative colitis (UC) develop an **acute severe ulcerative colitis (ASUC) episode,** requiring hospitalization, intravenous steroids (IVS) and supportive measures, associated with risk of mortality and an estimated risk of emergency colectomy of 30%. Additionally, it is known that following an episode of ASUC, **disease course** tends to be **more severe**. Therefore, follow-up and treatment strategy after induction of remission of patients with ASUC is extremely important.

However, although there is growing data about the medical management of ASUC episode or after ASUC episode in patients who do not respond to IV steroids, there remains a **lack of data** about the **optimal medical management** of patients presenting with an **ASUC episode and who respond to IV steroids (steroid-responsive ASUC)**. That is why we propose to do this study, whose global aim is to assess the course of steroid-responsive ASUC patients, stratified by the type of medical therapy offered following hospital discharge.

With this email, the Gastrenterology Department of Hospital Beatriz Ângelo (Portugal) would like to ask different European IBD centers to collaborate on this topic in a **retrospective, multi-center observational cohort study**. The primary goal is to compare the time until disease relapse/complication (defined by need for steroids, therapy escalation, hospitalization and colectomy) between patients treated with non-advanced (5-ASA/IMM) vs advanced therapy (biologics/small molecules), after a steroid-responsive ASUC episode. The secondary objectives are to compare each event separately, namely the time need for steroids, escalation of therapy, hospitalization and colectomy, as well as the percentage of time with inactive disease.

Each participating centre will be requested to retrospectively collect data on adult patients with an ASUC episode according to Truelove and Witts Criteria who responded to steroids according to Oxford Criteria, between 01/01/2010 and 31/12/2021.

Inclusion criteria

- Adult patients with a definitive diagnosis of ulcerative colitis, based on clinical, biochemical, endoscopic and histological findings;
- Patients who were hospitalized for an ASUC episode, according to Truelove and Witts Criteria (≥6 episodes of bloody diarrhea per day and at least one of the following criteria: heart rate ≥90 bpm, temperature ≥37.8ºC, hemoglobin ≤10.5 g/dL and/or C-reactive protein (CRP) ≥30 mg/L);
- Patients who responded to steroids, according to Oxford Criteria: complete responders (stool frequency < 3 per day) or incomplete responders (stool frequency: 3-8/d and CRP < 45 mg/L)

Exclusion criteria

- ASUC episode during pregnancy;
- Patients with Clostridioides difficile superinfection;
- Patients in who follow-up data cannot be retrieved.

According to our sample size calculation, our goal is to include at least 250 patients.

The final version of the study protocol that can be found attached and has been reviewed extensively by the Clinical Committee (ClinCom) of ECCO.

Who can collaborate?

- IBD centres with the possibility to retrieve data on UC patients hospitalized with ASUC and the necessary information about the follow-up and disease course.
- IBD centres who are willing to fill out an electronic clinical research form (eCRF) through **REDCap®** software for all included patients.
- IBD centres who are willing to verify themselves if approval by their local ethical committee and informed consent of the patient is mandatory in their jurisdiction for a retrospective non interventional study. If so, the IBD centre will be responsible for the submission to the local ethical committee as well as collection of the informed consent.

If you are interested in collaboration to this study, please contact catarina.bravoo@gmail.com by **September 20th 2024**, stating also 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 centres in your country.

We will aim for the submission of an abstract (with initial data) for ECCO 2025 and a full manuscript shortly thereafter. The publication list will consider the number of patients included in the study.

We truly hope that this retrospective study will be successful, may help selecting these patients' treatment and lead to an intense collaboration between centers.

Sincerely,

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