Dear colleagues,

Post-operative prophylaxis therapy is indicated for patients with Crohn's disease (CD) who are at high risk for recurrence. Anti TNF based therapies are considered the most effective strategies for preventing disease recurrence. However, some patients are intolerant to these therapies and about 20-30% of patients experience disease recurrence despite anti TNF treatment. Thus, there is an unmet need for additional treatment options.

In recent years, new biologic treatments have been introduced to our therapeutic armamentarium for patients with CD, these include anti integrins and anti IL12/23 antibodies. Clinical trials have demonstrated efficacy with these agents both in inducing and maintaining clinical and endoscopic remission, in both anti TNF naïve and experienced patients. Nonetheless, little is known about the efficacy of these newer biologic treatments for post-operative prophylaxis.

In this study, we aim to evaluate the efficacy of either vedolizumab or ustekinumab for clinical and endoscopic post-operative CD prophylaxis and to compare these strategies with anti-TNFs.

With this email, the IBD center at Rabin Medical Center would like to ask all European IBD centers to collaborate on this retrospective, multi-center cohort study. Each participating center will be requested to collect anonymized data on patients with CD who underwent a curative ileocectomy/right hemicolectomy and received post-operative prophylactic treatment with vedolizumab or ustekinumab or an anti TNF. Patients who received the treatment within 6 months of surgery, and had a post-op follow-up of at least 12 months can be included. The study protocol (attached) has been reviewed and approved by the Clinical Research Committee (ClinCom) of ECCO.

Who can collaborate?

- Centers which maintain a list of patients treated with biologic treatments and surgery
- Centers who have the ethical approval for collecting retrospective patient's data or are willing to get the local ethical committee approval for collecting these retrospective anonymized data

If you are interested in collaboration to this study, please contact mayago1@clalit.org.il/ henitya@clalit.org.il/ warditsh@clalit.org.il/ by 1.12.2020. The data will be documented in a specific EXCEL spreadsheet that will be sent to all participating centers. The study research contacts will be available for any clarifications or queries arising during data collection.

Please forward this email to other IBD centers/doctors in your country. We intend to submit an abstract for ECCO 2021 and a full manuscript shortly thereafter. The publication list will take into account the number of patients included in the study. All collaborators will be included as authors and will be traceable through a PubMed search.

Looking forward to join forces in this important initiative,

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