the two groups. Patients with active fistulas had significantly more work impairment (median 0.20 vs. 0.10, \( p = 0.010 \)). Furthermore, patients with active fistulas held more negative views concerning the effects of their illness on daily functioning (adjusted \( \beta = 0.78; \) CI(95%) = 0.28 to 1.27 (95% CI), \( p = 0.003 \)). No differences were found in coping strategies between the two groups.

**Conclusions:** Patients with active perianal fistulas have a lower physical health, experience more work impairment and perceived more illness consequences compared with CD patients without perianal fistulas, which is important for the gastroenterologist to consider when treating these patients.

**Reference**

### P446
**Patient and public involvement in a clinical trial for perianal Crohn’s fistula**

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**Background:** The James Lind Alliance agreed a research agenda in IBD, involving 400 patients, carers and charitable representatives. “What is an optimal treatment strategy for perianal Crohn’s disease and what individual factors determine this?” was prioritised fifth on the IBD research agenda.1 This question is now the subject of the EvaluatiNg Goal Directed MANagement (ENiGMA) trial for patients with fistulising perianal Crohn’s Disease (pCD).

**Methods:** Four patient co-applicants have been integral to all meetings and teleconferences of the ENiGMA study group. These patients have influenced trial design and help prioritise outcomes, Figure 1.

**Results:** (a) Initiation of the trial: A formal patient and public involvement exercise was carried out to present the trial proposal to 23 patients with perianal Crohn’s fistula and to assess their views on all aspects of the study. Patients agreed that a prospective cohort study design would be easy to recruit into, indicating that they may even wish to transfer care between institutions to allow participation. Quality of life and patient-reported outcomes were felt to be important and patients attending felt MYMOP, a method to allow patients to set their own treatment goals, should be introduced into routine clinical practice as a means of exploring patients’ wishes in a structured way. The burden of the suggested questionnaires was deemed reasonable and patients completed the questionnaires within 15 min. In addition, an anonymised perineal photograph, as means of classifying the type/stage of fistulating pCD, was deemed both acceptable and useful. (b) Development of the trial: Two separate workstreams were developed from the initial PPI involvement day. The first was a core outcome set for fistulating pCD, which has recently been submitted for publication and involved 83 patients within one of the three stakeholder groups. The second was the development of a specific Crohn’s anal fistula quality of life (CaF-QoL) score. CaF-QoL is in the second phase (of five) of development and is due to be completed in April 2018. (c) Future directions: The ENiGMA study includes the final consensus of front-running options in trial development; patients will form one of the three stakeholder groups in final trial design. One of our patient representatives (SB) edits the ENiGMA Collaboration’s newsletter.

**Conclusions:** Patients and representatives of patient groups have been partners in ENiGMA from conception through study development and design, and remain integral to delivery of this study proposal.

**Reference**

### P447
**Infliximab trough levels are decreasing overtime in patients with inflammatory bowel disease on maintenance treatment with infliximab**

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**Background:** The measurement of infliximab trough levels (IFX-TLs) and antibodies to infliximab (ATIs) has been suggested as an important parameter for the optimisation of treatment in patients with inflammatory bowel disease (IBD). We aimed to estimate the patterns overtime of IFX-TLs and ATIs in IBD patients on maintenance treatment with IFX.

**Methods:** Consecutive patients on maintenance treatment with IFX were included. Two different measurements of IFX-TLs x ATIs were made (ELISA, Eagle BioSciences) with a 10-month interval using serum samples drained before IFX infusion. From the same samples certain biomarkers (haemoglobin, ESR, CRP, platelets, albumin) were measured and at the same time quality of life (SIBDQ) and clinical disease activity (Harvey-Bradshaw Index (HBI) for Crohn’s disease (CD), simple colitis activity index (SCAI) for ulcerative colitis (UC)) were assessed.
P448
Remission induction therapy with tacrolimus and biological combination therapy for severe ulcerative colitis
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Background: Remission induction therapy with tacrolimus (TAC) and biological agents (bio) has been shown to be effective for ulcerative colitis (UC). Monotherapy with bio or TAC may fail to achieve remission, and surgical treatment is required in some patients. We perform combined TAC and bio therapy for remission induction after hospitalising patients if remission cannot be achieved with TAC or bio monotherapy alone, although such cases are rare. We performed this study to clarify the efficacy and problems of concomitant treatment with TAC and a biological agent.

Methods: The subjects were 11 patients with UC who underwent combined TAC and bio therapy for the induction of remission at our hospital from April 2000 to August 2017. We classified the patients into a remission group and a non-remission group, and we assessed the recurrence rate in the remission group. Remission was defined as a reduction in the first measurement increased their median IFX-TLs from 1.47 to 8.5 μg/ml, whereas patients with stable IFX dose showed a significant reduction (from 5.65 to 3.8 μg/ml, p < 0.0001). Six IB patients (9.4%) had positive ATIs (>10 AU/ml) in measurement A 4 of which were neutralised in measurement B (2 after dose intensification), while ATIs were positive in two patients at measurement B although they were negative at the initial one. Regarding the biomarkers only CRP levels were significantly increased in measurement B compared with measurement A [0.33 (0.3–4.4) mg/dl vs. 0.31 (0.3–3.8) mg/dl, p = 0.02]. No significant differences in the two measurements of the other biomarkers, clinical activity indices and SIBDQ were found.

The reduction of IFX-TLs among the two measurements was significantly correlated with the increase of CRP levels (r = 0.29, p = 0.02). No other correlations of the examined parameters including the use of immunomodulators was found (all p > 0.05).

Conclusions: IBD patients on maintenance treatment with infliximab show decreasing patterns of IFX-TLs overtime associated with increasing CRP levels. These results probably provide an underlying mechanism for the known loss of efficacy of IFX in many patients and suggest the need for early treatment optimisation.

P449
Double assessment of ileal pouch-anal anastomosis before ileostomy reversal
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Background: Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the ‘gold standard’ procedure for patients with ulcerative colitis (UC) requiring surgical intervention. Anastomotic leak after IPAA is a major complication associated with high morbidity due to pelvic sepsis, as well as increased probability for pouch dysfunction and failure in the future. Moreover, the management of the leaking anastomosis remains challenging. Thus, defunctioning ileostomy is performed by many surgeons as a step for a two- or three-stage IPAA construction. The aim of this study is to present the methodology and results of the routine double assessment of IPAA integrity which is performed in our institution before ileostomy reversal.

Methods: This is a retrospective observational study of 61 UC patients (39 males/22 females) who underwent either a two-stage or three-stage procedure between 2010 and 2016. A diverting ileostomy was created in all patients after IPAA construction, which was reversed at least 3 months later. Three-stage procedure (subtotal colectomy with end ileostomy first) was performed in patients with acute severe colitis resistant to rescue therapy. An experienced colorectal surgeon was in charge during every surgical procedure. All patients underwent a double assessment of IPAA integrity before stoma closure: Fluoroscopic water-soluble enema study (FES) and pouch endoscopy (PE). Postoperative signs and symptoms of pelvic sepsis, septic complications (abscesses, fistulae) as well as imaging studies and endoscopic findings during follow-up were recorded.

Results: Of the 61 patients (39 males) with a median age of 35 years (range from 16 to 70 years) who underwent IPAA, 15 (24.6%) underwent a 3-stage surgical procedure and the remaining a 2-stage procedure. FES and PE evaluation identified no patient with evidence of