**Abstract O8 Table 1** Per protocol outcomes, including cross-over (Primary endpoints in bold)

| | Remission 10w | Remission maintained to 6 m | Remission maintained to 12 m | Rem. &/or response 10w | Remission 4wk |
|---|---|---|---|---|---|
| AB/HCQ | **7/27** | **6/24 (plus 3 10wk responders in rem @ 6m)** | **3/23 (plus 1 10wk responder in rem @ 12m; plus 1 clin rem but WD UTI)** | 15/27 | 8/30 |
| Budesonide | **10/34** | **1/32 P=0.035 (preset significance threshold of P= 0.02 to allow for multiple testing)** | **1/31** | 13/34 | 9/37 |

(Entocort CR 9 mg/day 8 weeks, then 6 mg/day 2 weeks and 3 mg/day 2 weeks) or antibiotics/hydroxychloroquine (AB/HCQ) - oral ciprofloxacin 500 mg bd, doxycycline 100 mg bd, hydroxychloroquine 200 mgs tds for 4 weeks, followed by doxycycline 100 mg bd and hydroxychloroquine 200 mgs tds for 20 weeks. Use of anti-TNF in the previous 3 months was an exclusion. Primary endpoints were remission (CDAI </=150) at 10 weeks, remission maintained to 24 weeks, and remission maintained to 52 weeks. Patients not responding by 10 weeks were invited to cross-over onto the alternative therapy.

**Results** 59 patients were recruited across 8 sites, lower than target (100) as recruitment slowed due to widening access to biologics. Including cross-over, 39 patients received AB/HCQ and 39 received budesonide. No significant differences were seen comparing AB/HCQ with budesonide at 10, 24 or 52 weeks on either intention-to-treat or per protocol analysis (see table 1). Withdrawals by 10 weeks due to adverse events were seen in 16 AB/HCQ and 7 budesonide. When patients on AB/HCQ who responded at 10 weeks and later remitted were included, 9/24 patients were in remission at 24 weeks and 4/23 at 52 weeks. No correlation was seen between response to AB/HCQ and ASCA/OmpC status.

**Conclusions** The long term remissions seen with AB/HCQ are encouraging and justify a phase 3 study.

## O9 STOP-COLITIS PILOT: PROSPECTIVE, OPEN-LABEL, RANDOMISED STUDY COMPARING NASOGASTRIC VERSUS COLONIC FMT DELIVERY IN ULCERATIVE COLITIS

[1]Mohammed Nabil Quraishi*, [2]Mehmet Yalchin, [3]Clare Blackwell, [2]Jonathan Segal, [1]Naveen Sharma, [1]Peter Hawkey, [1]Victoria McCune, [4]Catherine Hewitt, [4]Natalie J Ives, [4]Shrushma Loi, [4]Laura Magill, [1]Susan Manzoor, [5]Konstantinos Gerasimidis, [6]Nicholas J Loman, [7]Christel McMullan, [7]Jonathan Mathers, [8]Christopher Quince, [9]Nicola Crees, [10]Richard Hansen, [2]Ailsa L Hart, [3]Daniel R Gaya, [1]Tariq H Iqbal. *[1]University of Birmingham Microbiome Treatment Centre, Birmingham, UK; [2]Department of Gastroenterology, St Marks Hospital, UK; [3]Gastroenterology Unit, Glasgow Royal Infirmary, UK; [4]Clinical Trials Unit, University of Birmingham, UK; [5]Human Nutrition, University of Glasgow, Glasgow, UK; [6]Institute of Microbiology and Infection, University of Birmingham, Birmingham, UK; [7]Institute of Applied Health Research, University of Birmingham, UK; [8]Warwick Medical School, University of Warwick, UK; [9]Crohn's and Colitis UK, UK; [10]Department of Paediatric Gastroenterology, Royal Hospital for Children Glasgow, Glasgow, UK*

10.1136/gutjnl-2020-bsgcampus.9

**Introduction** Although faecal microbiota transplantation (FMT) appears to hold therapeutic potential for ulcerative colitis (UC), the optimal administration route and dose of FMT is unknown. This pilot trial aimed to identify the optimal route of administration to further test in an RCT.

**Methods** In this prospective, three-centre, open-label, randomised study (STOP-Colitis pilot), we compared delivery of FMT via the naso-gastric (NG) or colonic (COLON) route in adult patients with active UC. Participants were administered 8 infusions of FMT over an 8 week period. Clinical response was defined as ≥3 point and ≥30% reduction in Mayo score at week 8 compared to baseline. Clinical remission was defined as Mayo score of ≤2, with no subscore >1 at week 8. The primary outcome was based on clinical response and safety at weeks 8 and 12, along with qualitative assessment of acceptability.

**Results** 30 participants were randomised between March 2018 and April 2019; 16 to NG; 14 to COLON. 8 in NG arm and 2 patients in the COLON arm withdrew from the study before completion. Clinical response was achieved in more participants who received FMT via COLON compared with NG (9/12 [75%] vs 2/8 [25%]; adjusted relative risk [RR] 2.94 [95% CI, 0.84, 10.30]). Clinical remission was observed in more participants undergoing FMT via COLON compared to NG (6/12 [50%] vs 2/8 [25%] respectively; RR 1.89 [95% CI, 0.51, 6.99]). IBDQ and SF-36 scores at week 8 and 12 were similar in NG and COLON groups. Qualitative analysis showed greater patient and clinician acceptability for colonic delivery. There were three serious adverse events (one considered a serious adverse event) in 2 participants in the NG arm, and none in the COLON arm.

**Conclusion** This pilot study suggests that in patients with active UC, FMT delivered via the COLON route appears to be safe and better tolerated with signals suggesting greater efficacy compared to the NG route. A randomised, double-blind, placebo-controlled trial of colonic delivery of FMT is now underway to determine clinical efficacy and safety.

## O10 NORMALISATION OF CALPROTECTIN WITHIN 12-MONTHS OF DIAGNOSIS IS ASSOCIATED WITH REDUCED DISEASE PROGRESSION IN CROHNS

Nikolas Plevris*, James Fulforth, Philip Jenkinson, Spyros Siakavellas, Mathew Lyons, Rebecca Pattenden, Ian Arnott, Gareth Jones, Charlie Lees. *Edinburgh IBD Unit, Edinburgh, UK*

10.1136/gutjnl-2020-bsgcampus.10

**Introduction** Faecal calprotectin (FC) demonstrates excellent correlation with endoscopic inflammation. In addition, a treatment-decision algorithm for Crohn's disease (CD) incorporating FC outperforms and improves 12-month mucosal healing