Abstract OFR-8 Figure 1

OFR-9 AN RCT OF AUTOLOGOUS STEM-CELL TRANSPLANTATION IN TREATMENT REFRACTORY CROHN'S DISEASE (LOW-INTENSITY THERAPY EVALUATION): ASTICLITE

¹James Lindsay*, ²Shahida Din, ³Chris Hawkey, ⁴Danny Hind, ⁵Peter Irving, ⁶Alan Lobo, ³Yash Mahida, ³Gordon Moran, ⁶Miles Parkes, ⁷Jack Satsangi, ⁸Sree Subramanian, ⁴Lizzie Swaby, ⁷Simon Travis, ⁴John Snowden. ¹Barts Health NHS Trust, London, UK; ²Western General Hospital, Edinburgh, UK; ³University of Nottingham, Nottingham, UK; ⁴University of Sheffield, Sheffield, UK; ⁵Guy's and St Thomas' Hospital, London, UK; ⁶Cambridge University Hospitals, Cambridge, UK; ⁷Oxford University Hospitals, Oxford, UK; ⁸Royal Liverpool University Hospital, Liverpool, UK

10.1136/gutjnl-2021-BSG.6

Introduction Reports of benefit from HSCT were tempered by the ASTIC trial which failed its ambitious primary endpoint and reported high toxicity. Subsequent reports suggest that HSCT achieves complete mucosal healing in 50%, and that toxicity relates to the cyclophosphamide dose.

Design A UK multi-site RCT comparing low intensity HSCT with standard of care (SOC) in patients with active CD at endoscopy (SESCD ulcer score ≥ 2) refractory to 2 biologic classes. Planned recruitment was 99 patients randomised 2:1 to HSCT versus SOC. The primary endpoint was centrally read endoscopic remission (SESCD ulcer subscore of 0) without requirement for surgery or death at week 48.

Results The trial was halted due to unexpected SAE after 23 patients (13 HSCT, 10 SOC) had been randomised. The coronavirus pandemic prevented some outcome assessments. Patients had advanced disease: mean (SD) CD duration 13.9 (7) years; CDAI at baseline 337.5 (182.4) with 20 (91%) having undergone surgery and 9 (43%) having a stoma. All patients contributed to the safety analysis. The primary outcome using central reading was available for 7/10 HSCT and 6/9 SOC patients. Absence of endoscopic ulceration without surgery or death was reported in 3/7 (43%) HSCT patients compared to 0/9 (0%) SOC patients. Centrally read SESC (mean (SD)) was 11.8 (8.7) and 10.1 (5.7) at baseline compared to 2.8 (2.9) and 18.7 (9.1) at week 48 in the HSCT and SOC groups respectively. Clinical remission (CDAI <150) occurred in 57% and 0% of patients in the HSCT and SOC groups at week 48. SAE were more frequent after HSCT (39 in 13 (100%) patients) than SOC (15 in 4 (40%) patients).

Importantly, 10 SUSARs were reported in 6 HSCT patients including 3 cases of delayed renal failure due to thrombotic microangiopathy (TMA). Two patients in the HSCT arm died. **Conclusion** HSCT using a low intensity regimen results in meaningful reduction in endoscopic disease activity with some patients experiencing resolution of ulceration. However, the incidence of serious adverse events makes the regimen used in this trial unsuitable for future clinical use.

This project (15/178/09) is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership. The views expressed in this publication are those of the author(s) and not necessarily those of the MRC, NIHR or the Department of Health and Social Care.

OFR-10 ADMISSION MODEL FOR INTENSIFICATION OF THERAPY IN ACUTE SEVERE COLITIS (ADMIT-ASC)

¹Alex Adams*, ¹Vipin Gupta, ²Waled Mohsen, ¹Thomas Chapman, ²Deloshan Subhakaran, ²Pradeep Ramaswamy, ¹Oxford IBD Cohort Investigators, ³Vineet Ahuja, ¹Simon Travis, ¹Jack Satsangi. ¹Translational Gastroenterology Unit, University of Oxford, Oxford, UK; ²Digestive Diseases Unit, Gold Coast University Hospital, Australia; ³Department of Gastroenterology, All India Institute of Medical Sciences, New Delhi, India

10.1136/gutjnl-2021-BSG.7

Introduction Acute severe colitis (ASC) is an important cause of morbidity and mortality in UC, requiring hospitalisation and often colectomy. Accepted management is protocolised response assessment at Day 3 of IV steroid treatment. If steroid non-responders could be identified at all earlier stage, intensification may be possible prior to Day 3. It is also unclear whether ASC outcomes have changed over the past 25 years and we aimed to examine this.

Methods We examined ASC cohorts across 3 continents to produce an accurate predictor of steroid response. All patients received protocolised treatment including first-line IV corticosteroids, and endoscopic (UCEIS) scoring. Factors associated with requirement for rescue therapy, colectomy during admission, and the following year, and a composite measure of steroid response were identified by logistic regression in 131 adult ASC admissions in Oxford, UK, between 2015-9.