Determining the optimal route of faecal microbiota transplant in patients with ulcerative colitis: the STOP-Colitis pilot RCT

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Plain language summary

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Plain language summary

Ulcerative colitis, a chronic inflammatory condition affecting the colon, results from the body's immune response to imbalance in colonic microbes (microbiota). Faecal microbiota transplantation involves transferring processed donated stool samples from carefully screened healthy donors to ulcerative colitis patients aiming to correct the imbalance and reduce inflammation.

There have been four trials comparing faecal microbiota transplant with placebo (dummy no treatment) to treat ulcerative colitis, and one which investigated faecal microbiota transplant with dietary intervention. Three of these studies showed encouraging benefit for faecal microbiota transplant. However, these studies varied in the methods used, with faecal microbiota transplant delivered either to the stomach or colon, or both.

The aim of this study was to identify the best route of faecal microbiota transplant administration before undertaking a large-scale trial comparing faecal microbiota transplant with placebo. Between March 2018 and 30 April 2019 ulcerative colitis patients from three hospitals were randomly allocated to receive faecal microbiota transplant via either a tube inserted through the nose into the stomach on 4 consecutive days repeated after a month (nasogastric group; 16 participants) or by colonoscopy followed by 7 weekly enemas (COLON group; 14 participants).

Faecal microbiota transplant was well accepted, with both patients with ulcerative colitis and healthcare staff stating a preference for the colonic route. Only 8 of 16 in the nasogastric group completed the study compared to 12 of 14 in the COLON group. Altogether, 9/12 (75%) in the COLON group improved compared with 2/8 (25%) in the nasogastric group. The majority of participants [11/14 (79%) COLON vs. 11/16 (69%) nasogastric] had mild, short-lived side effects following faecal microbiota transplant. There were three serious adverse events. Faecal calprotectin (indicating colonic inflammation) fell in responders and stool samples showed an increase in the number of microbial species after faecal microbiota transplant.

At the end of the study, a recommendation was made by the Independent Oversight Committee to proceed to a large placebo-controlled randomised trial using the colonic route.

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