Inflammatory bowel disease III

PWE-224 CHALLENGES IN RECRUITING TO CLINICAL TRIALS IN THE UK: THE TOPPIC EXPERIENCE

doi:10.1136/gutjnl-2012-302514d.224

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Introduction The Trial of Prevention of Post-operative Crohn’s disease (TOPPIC) is a multi-centre, randomised, Medical Research Council (MRC) funded, controlled trial of mercaptopurine (MP) vs placebo in preventing post-operative recurrence. It is the largest and only double-blinded trial conducted to date assessing thiopurine treatment in this setting. To complete the study in five centres we assumed that 60% of eligible patients would be enrolled into the study. Our experience of the challenges to recruitment has relevance to all other clinical trials in the area.

Methods Patients undergoing intestinal resection for Crohn’s disease (CD) were prospectively recruited and randomised (1:1) within 3 months of surgery to either placebo or 1.5 mg/kg/day MP. 254 patients are sought to detect a 20% difference with 80% power between the two groups. The primary outcome measures to assess the ability of MP to delay or prevent post-operative recurrence. This was assessed clinically at 12 study visits over 36 months and endoscopically at 12 and 36 months. Recruitment is due to finish in 2012.

Results The initial enrolment of patients was disappointing with only 60 patients recruited at 22 months (predicted 150 patients). Within the study centres anti-TNF use increased over the same period fivefold (p The study was therefore extended for a further 18 months from 5 Scottish centres, to involve 25 new sites across England and Wales. As of February 2012 223 patients have been randomised representing 20.5% of the 1085 patients undergoing resection at participating centres. Of those not randomised, 550 (49%) were ineligible and 243 (22%) declined pre-screening, 71 (6%) were ineligible/declined during screening. Of the 550 patients ineligible pre-screening 158 (30%) had a stoma, 110 (21%) were not included for reasons not specified, 55 (10%) had a condition the clinician felt placed them at unacceptable risk, 53 (10%) had MP hypersensitivity, 32 (6%) had no known diagnosis of CD, 28 (5%) failed to have ileocolonic resection within 3 months, 19 (4%) had active or untreated malignancy. The remainder 14% consisted of multiple other factors; including previous pancreatitis, and length of small bowel resected. Of the 44 randomised patients whom have since dropped out since randomisation; 23 withdrew early from the trial, 13 were lost to follow-up, six other reasons not specified and one mortality from coronary heart disease.

Conclusion Our experience illustrates a number of challenges in investigator lead studies in IBD. Although we had accurately predicted the number of resections our initial projections had dramatically underestimated the proportion of patients willing or eligible to participate in a placebo controlled study. This study has however, highlighted the merits of multi-centre collaboration, not least due to the acceptance onto the NIHR portfolio.

Competing interests None declared.

PWE-225 EFFICACY OF Faecal LACTOFERRIN IN IBD AND IBD: A COMPARATIVE STUDY

doi:10.1136/gutjnl-2012-302514d.225

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Introduction Faecal lactoferrin (FL) has been proposed as a non-invasive diagnostic tool in IBD. This is the first study conducted in a UK outpatient setting comparing simple colitis index (SCI) for ulcerative colitis (UC) and Harvey Bradshaw index (HBI) for Crohn’s disease (CD) against FL concentration in IBD and IBS patients.

Methods From an IBD outpatient clinic, stool samples were collected and concurrent disease activity recorded for UC, CD, IBS patients along with samples from healthy volunteers. Using IBD-Scan®, a quantitative ELISA, FL concentration was measured. Each participant’s recorded clinical index at time of collection was compared against calculated FL concentration to assess clinical efficacy of FL in determining disease status in IBD and in differentiating IBD from IBS.

Results Spearman’s correlation for correlation between LF and clinical score indices: 0.027 (p<0.05).

Conclusion FL is useful in staging of IBD and in differentiating IBD from IBS.

Abstract PWE-225 Figure 1 Lactoferrin plotted on a log scale for UC, CD, IBS and control groups respectively.