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A PRAGMATIC MULTICENTRE RANDOMISED CONTROLLED TRIAL COMPARING STAPLED HAEMORRHOIDOPEXY TO TRADITIONAL EXCISIONAL SURGERY FOR HAEMORRHOIDAL DISEASE. THE ETHOS TRIAL.

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Introduction: Haemorrhoidal disease is common in all age groups from the mid-teens onwards. Approximately 25,000 procedures were performed in England during 2006/2007 on hospital day-cases or inpatients[1]. Current interventions include traditional excisional surgery (TH) and stapled haemorrhoidopexy (SH). Uncertainty remains about how they compare[2-6]

The primary aim of eTHoS is to assess whether there is a difference between SH and TH[7] for the treatment of haemorrhoidal disease (grades II, III, and IV) on patient centred quality of life profile. Treatment costs will also be examined.

Method: Participants were randomly allocated to one of two study groups in equal proportion (SH or TH). Thirty-one sites from within the UK took part in the study. Patients, aged 18 year or older, with a diagnosis of circumferential haemorrhoids grade II-IV were eligible to take part. Randomisation utilised a minimisation algorithm which incorporated centre, grade of haemorrhoid(s), baseline EuroQol 5 Dimension health status questionnaire (EQ-5D) score and gender.

The primary outcome for this study is patient-centred, quality of life profile (area under the curve (AUC) derived from EQ-5D data collected at baseline, 1 week, 3 weeks, 6 weeks, 12 months and 24 months; Economic, incremental cost per quality adjusted life year (QALY) gained with QALYs were based on the responses to the EQ-5D.

A sample size of n=338 per group was calculated to provide 90% power to detect a difference in the mean area under the quality of life curve of 0.25 standard deviations (derived from EQ-5D score measurements, with a significance level of 5%). 400 were to be randomised to each group.

Results: The eTHoS trial closed for recruitment in August 2014 and is in follow-up. A total of 1129 patients were approached to take part in the trial. 777 participants were randomised (388 to TH and 389 to SH) with 7 post-randomisation exclusions from each group.

Conclusion: This trial is currently the largest of its type in the world. Our results will be reported in full in October 2016 to The National Institute for Health Research.

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Disclosure of Interest: None Declared