Study Centre No

eTHoS Log Book

Hospital No	Date for Admission	Name	Date of Birth	Consent Y/N *	Baseline Data entered	Randomised T or S	Theatre Informed of surgery

* If No, complete ineligible/declined form

Version 1, February 2010

eTHoS INELIGIBLE OR DECLINED FORM

Outline data on patients who are ineligible or who decline participation

Q1 **Date of attempted recruitment** D D / M M / Y Y Y Y

Q2 **Year of Birth** Y Y Y Y

Q3 **Gender** Male ☐ Female ☐

Q4 **Diagnosis of haemorrhoids**

Grade II ☐ Grade IV ☐

Grade III ☐

Q5 **Reasons for non-inclusion - tick all that apply**

Previous surgery for haemorrhoids (except Rubber Band Ligation or HALO)	☐
Prior surgical treatment for anal sphincter injury repair, or symptomatic incontinence	☐
Peri-anal sepsis	☐
Known inflammatory bowel disease	☐
Malignant gastrointestinal disease, within the last 5 years	☐
Medically unfit for surgery or for completion of the trial	☐
Unable to complete study questionnaires	☐
Pregnant	☐
Patient does not want to participate in the study:	☐
If provided – the reason the patient does not want to participate:	
Other	☐

If other, please state:

Signature: _____

BASELINE CRF

eTHoS
either Traditional Haemorrhoidectomy or Stapled Haemorrhoidopexy for Haemorrhoidal Disease

Study number | | | | | |

***PATIENT DETAILS* (Sticker may be used below)**

Title: ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

First name

Surname

Date of birth D D / M M / Y Y Y Y

NHS number

CHI number

Address (use hospital label if available)

Contact telephone no.

Mobile no.

CONSULTANT DETAILS

Initials | | | Surname

GP DETAILS

Initials | | | Surname

Address

Telephone no

Date of Baseline Assessment D D / M M / Y Y Y Y

MEDICAL HISTORY

Co-morbidities

Bleeding disorders ☐

Please specify bleeding disorder

Systemic medications related to increased risk of bleeding or reduced wound healing

Aspirin ☐ Warfarin ☐ Clopidogrel ☐ Steroids ☐

Immunosuppressants ☐ Other ☐

If Other, please specify

CLINICAL DATA

Weight (kgs)

Height (cm)

Has the patient had previous rubber band ligation (RBL)? Yes ☐ No ☐

If Yes, how many episodes?

Date of most recent RBL procedure D D / M M / Y Y Y Y

Has the patient previously had the HALO procedure? Yes ☐ No ☐

If Yes, how many episodes?

Date of most recent HALO procedure D D / M M / Y Y Y Y

PLANNED date of eTHoS surgery D D / M M / Y Y Y Y

Please ensure that the ACTUAL date of surgery is tracked and added to the study database as soon as known, to ensure that follow up questionnaires are triggered correctly

RANDOMISATION INFORMATION

Telephone Randomisation Service Number [redacted]

Web Address www.charttrials.abdn.ac.uk/ethos

Inclusion Criteria

- Patients with grade II, III or IV haemorrhoids
- Patients aged 18 years or older
- Written informed consent obtained

Exclusion Criteria

- Previous surgery for haemorrhoids (except RBL or HALO)
- Previous surgery for sphincter injury, or symptomatic incontinence
- Peri-anal sepsis
- Known inflammatory bowel disease
- Malignant gastrointestinal disease, within the last five years
- Medically unfit for surgery or for completion of the trial
- Pregnant women

Confirm patient is eligible ☐

YOU WILL NEED THE RESPONSES TO THE EQ-5D (A1-A5) FROM THE PARTICIPANT BASELINE QUESTIONNAIRE, GENDER AND GRADE OF HAEMORRHOIDS, BEFORE UNDERTAKING THE RANDOMISATION STEP

If possible, prior to randomising a patient, please enter all Baseline CRF and patient questionnaire data via the eTHoS website.

Grade of Haemorrhoids Grade II ☐ Grade III ☐ Grade IV ☐

Gender Male ☐

Female ☐

Patient Study Number ☐☐☐☐☐

Participant has been randomised to: SH ☐ TH ☐

eTHoS GP letter and information sheet

<< DATE >>

Dr GPFName GPSName
GPAddress1
GPAddress2
GPAddress3
GPAddress4
GPPostCode

Patient Study Number:

Dear Dr GPSName

eTHoS (either Traditional Haemorrhoidectomy or Stapled)

Patient: Title FName SName Ref No DOB Address1 Address2 Address3 Address4 PostCode

A multicentre UK-wide research study, funded by the National Institute for Health Research Health Technology Assessment Programme is investigating which haemorrhoidal operations are the most clinically and cost-effective for patients with haemorrhoids grade II, III and IV. CentreHosp is one of the participating sites. The trial is needed because there is uncertainty about which type of surgery (stapled haemorrhoidopexy or conventional excisional surgery) is most effective for these patients.

All participants who consent will be followed up and those who are eligible will be randomised to a particular type of surgery. Patients who have grade II (and who have already failed two episodes of rubber band ligation), grade III and IV haemorrhoids are included. We are following up patients after their operations, initially for two years, but hopefully also in the longer term, to identify recurrence rates. More detailed information about the study is provided overleaf.

Your patient has agreed to join the study. He/She has been randomised to one of the surgery groups. We will carry out postal follow up (from our study office in Aberdeen) by asking participants to complete questionnaires before surgery and at approximately 1, 3, 6 weeks and 12, 24 and 60 months after surgery. The questionnaires ask about general health and use of the health service as well as specific information about incontinence and haemorrhoidal symptoms.

We should not normally need to obtain any information from you. However, we would be grateful if you could contact telephone number [redacted] or email ethos@abdn.ac.uk if your patient changes address, is too ill to continue taking part, has an adverse event following their haemorrhoid surgery or dies.

If you would like to discuss any aspect of our trial, or require any further details, please do not hesitate to contact the eTHoS Study Office.

Yours sincerely

Jessica Wood
eTHoS Trial Manager

Prof. Angus Watson
eTHoS Chief Investigator

eTHoS GP INFORMATION SHEET

Title of project

Clinical and cost-effectiveness of two main treatment options for the surgical management of Haemorrhoids grade II, III and IV.

Background

Haemorrhoids are common in all age groups from mid-teens onwards. In England in 2006/2007 approximately 25,000 haemorrhoidal procedures were performed as hospital day-case or inpatient admissions, resulting in significant calls on health service resources. The treatment of haemorrhoidal disease is directed at relieving its related symptoms.

There are two major surgical treatments for haemorrhoids: the conventional excisional haemorroidectomy (traditional surgery) and the stapled haemorrhoidopexy. Improved understanding of the pathogenesis of haemorrhoids, increasing belief in the importance of preserving the anal cushions and greater awareness of the high incidence of complications associated with excisional haemorrhoidectomy led to the invention of the stapled haemorrhoidopexy procedure.

Two recent systematic reviews and an HTA monograph compared the two main surgical procedures, revealing that 95% of patients who received stapled surgery had less pain in the immediate post-operative period compared with the traditional surgery but equivalent complication and pain rates occurred with both procedures at day 21. Other potential advantages of stapled over conventional surgery include a reduction of operating time, hospital stay and time to return to work. However, uncertainties around complication rates and recurrence of symptoms and costs precludes its widespread use across the NHS. Over the long term there was a significantly increased rate of residual prolapse requiring re-intervention with stapled haemorrhoidopexy. eTHoS is therefore investigating what is the best surgical treatment for patients who have haemorrhoids grade II (with two episodes of rubber band ligation), III and IV who require surgery.

Brief outline of the study

Ethical approval has been obtained for this study Written consent has been obtained from participants. Participants will be reviewed in outpatients approximately six weeks after their surgery. Participants are sent postal questionnaires at approximately 1, 3 and 6 weeks and 12 and 24 months after their operation. Our main interest is in the improvement of haemorrhoidal symptoms, as reported by the patients themselves.

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DETAILS OF HOSPITAL ADMISSION AND COLORECTAL SURGERY

Study number | | | | | |

Date of admission D D / M M / Y Y Y Y

Actual Date of surgery D D / M M / Y Y Y Y

Was anticoagulant medication stopped prior to surgery? Yes ☐ No ☐ N/A ☐

If Yes, date medication stopped D D / M M / Y Y Y Y

Day case surgery planned? Yes ☐ No ☐

Initials of colorectal surgeon performing operation: | | |

Initials of supervising consultant surgeon (if applicable) | | |

Grade of operator

Consultant ☐

Specialty Doctor (SAS) ☐

Surgical Trainee ☐

Fellow ☐

Other ☐

If Other, please specify

If operation was supervised by a consultant, please tick the box ☐

Anaesthetist

Is there an anaesthetist present? Yes ☐ No ☐

If Yes, what grade?

Consultant ☐ Specialty Doctor (SAS) ☐ Fellow ☐ Registrar ☐

Other ☐ If Other, please specify

Type of anaesthesia

General ☐ General + LA Block ☐

Local only ☐ Spinal ☐ Other ☐

If Other, please give details

Surgical technique

Please confirm which surgical technique was carried out? (stapled, conventional or other):

Stapled ☐

Stapler used?

Ethicon Stapler ☐

Chex ☐

Covidien ☐

Other (state type of stapler below): ☐

Donut complete? Yes ☐ No ☐

Were skin tags removed? Yes ☐ No ☐

If Yes, how many?

Traditional ☐

Surgical approach?

Open (Milligan Morgan) ☐

Closed (Ferguson) ☐

Other (state type of surgical approach below): ☐

Were pedicles excised? Yes ☐ No ☐

If Yes, how many?

Other ☐ Please specify below which surgical technique was carried out:

Please confirm if the randomised technique was carried out? Yes ☐ No ☐

If NO, please explain why?

Was the surgical technique changed during the operation? Yes ☐ No ☐

If Yes, which surgical technique was initiated and why was it not completed?

Operation time

Please specify time of: (*using 24 hour clock*)

Entry into operating room H H : M M

Surgery start time *('knife to skin')* H H : M M

Surgery stop time *('procedure finishing')* H H : M M

Time of leaving operating room H H : M M

Intra-operative complications*

Yes ☐ No ☐

If yes, tick all that apply:

Anaesthetic ☐ Bleeding ☐ Need for blood transfusion ☐

Other ☐

If Other, please give details

Post-operative complications before discharge*

Post-operative bleeding ☐

Need for blood transfusion ☐

Other ☐

Pelvic sepsis ☐

Urinary retention (which requires catheterisation) ☐

If Other, please give details

**Please complete a Serious Adverse Event form if the patient is admitted to hospital or their hospitalisation admission is prolonged as a result of their haemorrhoid treatment or if the patient dies (any reason). The serious adverse event could be one of those expected, and listed above, or one that is not listed but deemed related to their participation in the eTHoS study.*

Date of discharge D D / M M / Y Y Y Y

6 WEEKS CRF

Study number ☐☐☐☐☐

Date of visit DD / MM / YYYY

Participant did not attend visit ☐

Clinical Examination

Examination carried out? Yes ☐ No ☐

If yes:

Haemorrhoidal tissue still present? Yes ☐ No ☐

If Yes, please grade Grade II ☐ Grade III ☐ Grade IV ☐

Proctoscopy carried out? Yes ☐ No ☐

Clinical findings
- Anal fistula ☐
- Anal stenosis ☐
- Residual anal skin tags ☐
- Anal fissure ☐
- Other ☐

If Other, please specify

Complications*

Has the patient experienced any of the following complications since discharge? Yes ☐ No ☐

If Yes please tick all that apply:

- Requirement for blood transfusion ☐
- Urinary retention (which requires catheterisation) ☐
- Wound discharge ☐
- Pelvic sepsis ☐
- Systemic complication related to haemorrhoids intervention(s) ☐
- Wound not completely healed (traditional haemorrhoidectomy only) ☐

Has the patient had any other related adverse events not listed above? Yes ☐ No ☐

If Yes, please give details

Please complete a Serious Adverse Event form if the patient suffers a medically significant serious complication, is admitted to hospital or their hospitalisation admission is prolonged as a result of their

haemorrhoid treatment or if the patient dies (any reason). The serious adverse event could be one of those expected, and listed above, or one that is not listed but deemed related to their participation in the eTHoS study.

Further interventions since discharge from surgery

Has the patient had any additional hospital visits or contacts since their haemorrhoid surgery approximately 6 weeks ago? Yes ☐ No ☐

If Yes, what (*please tick all that are appropriate and include the date of the intervention*)?

		Date
Further stapled haemorrhoidopexy	☐	D D / M M / Y Y Y Y
Further haemorrhoidectomy	☐	D D / M M / Y Y Y Y
Surgery for complications	☐	D D / M M / Y Y Y Y

If surgery for complications, please give details

Other colorectal surgery ☐

If other colorectal surgery, please give details

Indication for other colorectal surgery

Non surgical intervention ☐

If non surgical intervention, please give details

Was hospitalisation required for any of the above? Yes ☐ No ☐

If Yes, please provide admission and discharge date(s)

	Date of Admission	Date of Discharge
Admission One	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y
Admission Two	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y

Need for further treatment

Medical treatment

Is medical treatment required for persistent haemorrhoids or anal fissure? Yes ☐ No ☐

Pharmaceutical treatment prescribed? Yes ☐ No ☐

If Yes, please specify? GTN Paste ☐ Diltiazem Paste ☐

Other ☐

If Other, please specify

Have you discharged the patient from clinical follow-up? Yes ☐ No ☐

If No, go to the next section

Surgical treatment

Is further surgical treatment required for persistent haemorrhoids? Yes ☐ No ☐

If Yes, please specify below

Rubber band ligation Yes ☐ No ☐

Further stapled haemorrhoidopexy Yes ☐ No ☐

Further excisional haemorrhoidectomy Yes ☐ No ☐

Surgery for complications Yes ☐ No ☐

If surgery for complications, please specify

Other colorectal surgery ☐

If other colorectal surgery, please give details

Indication for surgery

Clinical appointment

Further clinical appointment required? Yes ☐ No ☐

If Yes, please state reason

WITHDRAWAL/ CHANGE OF STATUS

To be completed on withdrawal/change of status from study

Study No | | | | | |

Q1 Date of withdrawal D D / M M / Y Y Y Y

Reason for withdrawal

Q2 Participant decided to withdraw? (state reason)

Yes

Q3 Any medical reason for withdrawal? (please state reason)

What is participant withdrawing from?

Q4 Follow-up clinic visits? Yes ☐ No ☐

Q5 Completing questionnaires? Yes ☐ No ☐

Q6 Contact by telephone from a member of the eThoS team?

Yes ☐ No ☐

To Research Nurse/Study Office Staff: only complete if participant explicitly request this:

Q7 Relevant outcome data being collected (via hospital and GP records)?

Yes ☐ No ☐

Serious Adverse Event/Death Report Form

To be completed for any Serious Adverse Event (SAE) that is:

- **related (resulted from administration of any of the research procedures) and**
- **expected or unexpected (expected events are listed in section 4.4.1 of the protocol)**

ALL deaths must be recorded using this Report Form

eThoS Study No | | | | | |

Report Date D D / M M / Y Y Y Y

Participant Details:

Participant's Initials | | | |

Date of Birth D D / M M / Y Y Y Y

Q1. Type of event ***(cross all appropriate to adverse event – if any boxes are crossed the adverse event is "serious")***

Patient died	
Hospitalisation	
Prolongation of existing hospitalisation	
Persistent or significant disability or incapacity	
Life threatening	
Considered medically significant by the investigator	

Q2. Date of event D D / M M / Y Y Y Y

Q3. Brief details of adverse event

Q4. Is this an "expected" serious adverse event? Yes ☐ No ☐

Q5. Other relevant history (e.g. diagnostics, allergies, etc)

Q6. Place where adverse event took place/detected

Q7. Details of any intervention required

Assessment of whether the event resulted from administration of any of the research procedures:

Q8. Is it reasonably likely that the adverse event resulted from administration of any of the procedures required by eTHoS?

Yes ☐ No ☐

Q8a. Why?

Q9. Name and position of person making this judgement

Q9a. Date of assessment D D / M M / Y Y Y Y