

Staple-line bleeding reduction using a bioabsorbable reinforcement in day surgery stapled hemorrhoidopexy

Submission date 19/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/03/2010	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Antonio Brescia

Contact details

Via di Grottarossa 1035

Rome

Italy

00189

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Staple-line bleeding reduction using a bioabsorbable reinforcement in day surgery stapled hemorrhoidopexy: a randomised controlled trial

Study objectives

To demonstrate that the use of circular bioabsorbable staple-line reinforcement can reduce the intraoperative and the postoperative bleeding while performing a stapled hemorrhoidopexy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local medical ethics committee of the University Sapienza of Rome did not consider approval necessary as this trial is comparing two techniques and devices already in general use.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Symptomatic II-III grade haemorrhoids and rectal mucosal prolapse

Interventions

Patients treated in the Operative Unit of Day Surgery (Saint Andrews Hospital), were randomly assigned to stapled hemorrhoidopexy performed using

1. Group A: the stapler PPH33-01® (Ethicon Endo-Surgery, Inc. Cincinnati, OH) with a circular bioabsorbable staple-line reinforcement, seamguard BSG® (WL Gore & Associates, Flagstaff, AZ)
2. Group B: the more haemostatic stapler, PPH33-03® (Ethicon Endo-Surgery, Inc. Cincinnati, OH) only.

The total duration of follow up is 90 days. All patients receive proctological examinations on 15, 45 and 90 days post-operatively. Patients in group A also receive retroscopy on these days.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Intraoperative staple-line bleeding (yes or no)
2. Postoperative staple-line bleeding

Secondary outcome measures

1. Operative time (from the start to the end of anaesthesia)
2. Use of additional stitches for haemostasis
3. Postoperative pain and/or tenesmus, assessed by VAS (visual analogue scale) at 6 and 24 hours post-operatively
4. Patient satisfaction, assessed by questionnaire at day 45

Overall study start date

01/09/2009

Completion date

20/12/2009

Eligibility

Key inclusion criteria

1. Patients with symptomatic II-III grade haemorrhoids and rectal mucosal prolapse
2. Adults aged ≤ 65 , male or female

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

70

Key exclusion criteria

1. Patients without day surgery eligibility criteria
2. Concomitant ano-rectal disease (fissure, fistula, abscess, inflammatory bowel disease, rectal cancer)
3. Altered coagulation
4. Receiving anticoagulant-antiaggregant therapy

Date of first enrolment

01/09/2009

Date of final enrolment

20/12/2009

Locations

Countries of recruitment

Italy

Study participating centre

Via di Grottarossa 1035

Rome

Italy

00189

Sponsor information

Organisation

La Sapienza University of Rome (Italy)

Sponsor details

Faculty of Medicine and Surgery

Via di Grottarossa 1035

Rome

Italy

00189

Sponsor type

University/education

ROR

<https://ror.org/02be6w209>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Sapienza of Rome (Italy) - 2nd Faculty of Medicine and Surgery, Saint Andrews Hospital, Operative Unit of Day Surgery

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration