

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

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| 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

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration