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

Submission date	Recruitment status	[ ] Prospectively registered
19/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/03/2010	Urological and Genital Diseases	[ ] Record updated in last year

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 randomied controlled trial

Study hypothesis
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.

Condition
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

Overall study end date
20/12/2009

Eligibility

Participant 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

Participant 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

Recruitment start date
01/09/2009

Recruitment end date
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
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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