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

	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
<u> </u>	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

**Protocol serial number** N/A

# Study information

#### Scientific Title

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

# **Eligibility**

#### Key inclusion criteria

- 1. Patients with symptomatic II-III grade haemorrhoids and rectal mucosal prolapse
- 2. Adults aged  $\leq$  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

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes