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Comparing stapled hemorrhoidopexy vs. open and closed hemorrhoidectomy.

Submission date
09/02/2015

Recruitment status
No longer recruiting

Registration date
19/02/2015

Overall study status
Completed

Last Edited
13/01/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hemorrhoids, or piles, are swellings containing enlarged blood vessels found inside or around the anus and rectum. Most piles are mild and do not cause any problems, but symptoms include bright red blood found after passing a stool, an itchy anus and a viable lump hanging down from the anus. Many cases go away on their own or can be treated by lifestyle changes or medications. Surgical treatment can be recommended, however, if other treatments do not work or are not suitable. A hemorrhoidectomy involves cutting out the hemorrhoids under general anaesthetic. A stapled haemorrhoidopexy involves stapling the last section of the large intestine (anorectum), which reduces the supply of blood to the haemorrhoids and causes them to gradually shrink. There are a number of different hemorrhoidectomy and haemorrhoidopexy techniques. Recent studies have compared the open and closed hemorrhoidectomy techniques with each other and to Longo's hemorrhoidopexy technique, but no study has compared this new procedure with Parks' hemorrhoidectomy or analysed all three of these surgical procedures. In this study, we aim to compare all of these surgical treatments to determine whether Longo's technique is painless and associated with an earlier return to work.

Who can participate?
Patients with symptomatic hemorrhoids requiring surgical treatment who have not had a similar surgical procedure before.

What does the study involve?
The patients are randomly allocated to one of three groups. Those in group 1 undergo stapled rectal mucosectomy performed according to Longo's surgical technique. Those in group 2 undergo open hemorrhoidectomy performed according to Milligan-Morgan's technique. Those in group 3 undergo closed hemorrhoidectomy performed according to Park's technique. All patients are operated on under general anaesthesia. All patients report on their experience of pain (according to VAS scale) in a home diary every morning before taking pain medications. All patients are followed by a single proctological specialist for the first week, including a rectal digital exploration, and then at two weeks, and at one, three and four months, including endoscopic examination. Finally, patients are contacted by telephone interview with an ambulatory visit in case of recurrence or other late complications.

What are the possible benefits and risks of participating?
There are no benefits or risks for the participants.

Where is the study run from?
Università Campus Bio-Medico di Roma, Rome (Italy)

When is the study starting and how long is it expected to run for?
April 1998 to January 2007

Who is funding the study?
Investigator initiated and funded (Italy)

Who is the main contact?
Dr Valter Ripetti
v.ripetti@unicampus.it

Contact information

Type(s)
Public

Contact name
Dr Augusto Arullani

ORCID ID
http://orcid.org/0000-0003-0090-618X

Contact details
Via De Notaris 2b
Rome
Italy
00197

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised trial comparing stapled hemorrhoidopexy vs. open and closed hemorrhoidectomy.

Study objectives

In patients with hemorrhoids, do stapled hemorrhoidopexy compared to traditional hemorrhoidectom lead to better short and long term outcomes?'

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Università Campus Bio-Medico di Roma, 08/03/1999, ref: 9/99 ComET-CBM

Study design
Randomised interventional prospective 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Symptomatic hemorrhoids who were deemed to require surgical treatment

Interventions
180 patients into three arms of 60 patients. Stapled rectal mucosectomy was performed in group L according to the surgical technique described by Longo. Haemorrhoidectomy were performed according to Milligan-Morgan's and Park's techniques in group MM and P respectively. All patients were operated on under general anaesthesia

Intervention Type
Procedure/Surgery

Primary outcome measure
Intensity of postoperative pain at discharge at the first week and at the return to work activity

Secondary outcome measures
1. Duration of surgery
2. Analgesic intake in the first week
3. The intensity of postoperative pain after the first week, spontaneously, at defecation and at digital anal exploration
4. Days required for return to physical activity
5. Days required for complete healing (the disappearance of all symptoms linked to the surgical procedure)
6. The incidence of recurrence; and minor or major complications

Overall study start date
09/03/1999

Completion date
27/12/2014

Eligibility

Key inclusion criteria
Patients with symptomatic haemorrhoids who were deemed to require surgical treatment:
1. First haemorrhoidal surgery
2. Disease involving all three main peduncles
3. Residence within 50 km of the hospital (to allow close follow-up).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180 patients into three groups of 60 patients for group.

Key exclusion criteria
1. Patients underwent at associated or previous other surgical procedure for perianal pathologies
2. Patients with preoperative incontinence
3. Patients with with contraindication for general anaesthesia
4. Retired
5. Unemployed
6. Underage
7. Pregnant
8. Patient with major physical or mental comorbidities

Date of first enrolment
01/04/1999

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
Italy

Study participating centre
The Campus Bio-Medico University (Università Campus Bio-Medico di Roma)
Via Alvaro del Portillo 200
Rome
Italy
00128

Sponsor information

Organisation
The Campus Bio-Medico University (Università Campus Bio-Medico di Roma)

Sponsor details
Via Alvaro del Portillo 21
Rome
Italy
00128

Sponsor type
University/education

Website
http://www.unicampus.it/homepage

ROR
https://ror.org/04gqx4x78

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Italy)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No