Functional outcome after Perineal Stapled Prolapse resection (PSP) for external rectal prolapse

Submission date	Recruitment status No longer recruiting	Prospectively registered		
10/06/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/06/2009	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
23/10/2020	Digestive System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Franc Hetzer

Contact details

Department of Surgery Cantonal Hospital Rorschacherstr. 95 St. Gallen Switzerland 9007

- -

franc.hetzer@kssg.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Functional outcome after Perineal Stapled Prolapse resection (PSP) for external rectal prolapse: a prospective observational cohort study

Acronym

PSP

Study objectives

Faecal incontinence improves after perineal stapled prolapse resection (PSP).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Board of the Canton St. Gallen approved on the 1st December 2007 (ref: EKSG 01/124)

Study design

Prospective observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

External rectal prolapse

Interventions

For the PSP procedure spinal or general anaesthesia is recommended. In lithotripsy positioning the prolapse is completely pulled out and then axially cut open with a linear stapler at three and nine o'clock in lithotomy position. Finally, the prolapse is resected stepwise with the curved Contour® Transtar™ stapler at the prolapse's uptake. Operation duration is about 30 minutes and hospital stay is about 5 days. Peri-operative morbidity is prospectively assessed by a clinical visit at 4 weeks. Functional outcome is measured at 8 weeks by Wexner scores and recurrence rate is assessed by telephone interview at 6 and 12 months after surgery.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Faecal incontinence by Wexner score
- 2. Constipation by Rome criteria II
- 3. Urinary bladder dysfunction

Measured 2 months after surgery; recurrence rate is assessed at 6 and 12 months after PSP.

Secondary outcome measures

Post-operative morbidity, collected from 30 days after the intervention.

Overall study start date

01/12/2007

Completion date

01/12/2009

Eligibility

Key inclusion criteria

- 1. External rectal prolapse
- 2. Aged from 18 to 90 years, male and female

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

90 Years

Sex

Both

Target number of participants

50

Total final enrolment

32

Key exclusion criteria

Unfit for surgical intervention

Date of first enrolment 01/12/2007

Date of final enrolment 01/12/2009

Locations

Countries of recruitmentSwitzerland

Study participating centre Department of Surgery St. Gallen Switzerland 9007

Sponsor information

Organisation

Cantonal Hospital St. Gallen (Switzerland)

Sponsor details

Rorschacherstr. 95 St. Gallen Switzerland 9007 +41 (0)71 494 1111 franc.hetzer@kssg.ch

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/00gpmb873

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Cantonal Hospital St.Gallen (Switzerland) - covering incidental costs

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/03/2010	23/10/2020	Yes	No