

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

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

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
012009

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)

Primary study design

Observational

Study design

Prospective observational cohort study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

90 Years

Sex

All

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 recruitment

Switzerland

Study participating centre

Department of Surgery

St. Gallen

Switzerland
9007

Sponsor information

Organisation

Cantonal Hospital St. Gallen (Switzerland)

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

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