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

Submission date	Recruitment status	[_] Prospectively registered
10/06/2009	No longer recruiting	[_] 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

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)

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 recruitment
Switzerland

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