

Small bowel anastomosis of ileal conduit urinary diversions with the first sewing machine EndoSew™

Submission date 23/10/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/01/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/01/2014	Condition category Surgery	☐ 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
198/10

Study information

Scientific Title
Small bowel anastomosis of ileal conduit urinary diversions with the first sewing machine EndoSew™: a prospective single centre non-randomised pilot study

Study objectives

The small bowel (ileal) anastomosis of urinary diversions is performed by hand sutures in most centres. We test the first sewing machine EndoSew™ in a prospective single centre pilot trial. The aim is to prove feasibility of an open tight anastomosis by the sewing machine which - in the future - can be adopted in laparoscopic cystectomies and urinary diversions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kantonale Ethikkommission Bern approved on the 11th September 2010 (ref: 198/10)

Primary study design

Interventional

Study design

Prospective single centre non-randomised pilot study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Small bowel anastomosis

Interventions

Urinary diversion is performed by the sewing machine EndoSew™ in an open approach. Tightness of the suture is tested intra-operatively as well as 7 and 14 days post-operatively by loopogramms.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Feasibility of a suture by the sewing machine, measured at day 0 (at the time of operation)

Key secondary outcome(s)

1. Tightness, measured on day 0 (after the suturing), post-operative day 7 and post-operative day 14
2. Operating time, measured at day 0 (at the time of operation)

Completion date

01/08/2011

Eligibility

Key inclusion criteria

10 patients (aged greater than 18 years, either sex) scheduled for urinary diversion with an ileal conduit

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/12/2010

Date of final enrolment

01/08/2011

Locations

Countries of recruitment

Switzerland

Study participating centre

Urologische Universitätsklinik

Bern

Switzerland

3010

Sponsor information

Organisation

Inselspital, University Hospital Berne (Switzerland)

ROR

<https://ror.org/01q9sj412>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Inselspital, University Hospital Berne (Switzerland) - Department of Urology

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	01/11/2013		Yes	No