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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/01/2011	**Overall study status** Completed	
Last Edited 06/01/2014	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Prospective single centre non-randomised pilot study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

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
Small bowel anastomosis

Interventions
Urinary diversion is performed by the sewing machine EndoSew™ in an open approach. Thightness 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 measure
Feasibility of a suture by the sewing machine, measured at day 0 (at the time of operation)

Secondary outcome measures
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)

Overall study start date
01/12/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

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)

Sponsor details
Urology Department (Urologische Universitätsklinik)
Bern
Switzerland
3010

Sponsor type
Hospital/treatment centre

Website
http://www.insel.ch/

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

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	01/11/2013		Yes	No