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Clinical impact of early enteral versus parenteral nutrition following cystectomy and extended pelvic lymphadenectomy

Submission date 25/06/2010	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/07/2010	**Overall study status** Stopped	
Last Edited 18/07/2013	**Condition category** Cancer	

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
160/10

Study information

Scientific Title
Clinical impact of early enteral versus parenteral nutrition following cystectomy evaluated in a prospective randomised trial

Study objectives
Current opinion favours the use of postoperative early enteral over parenteral nutrition, although the benefits in cystectomy patients have never been clearly shown. The aim of this study is to evaluate the clinical impact of early enteral versus total parenteral nutrition following cystectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Canton of Bern (Ethikkommission des Kantons Bern) approved originally in November 2007. The trial was not started and approval was re-sought and granted in May 2010 (ref: 1394)

Study design
Prospective single centre double blind randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bladder cancer / invasive disease / Urology

Interventions
After cystectomy and extended pelvic lymphadenectomy patients are randomized into one of the following groups:
1. Group A: parenteral nutrition is given for 7 days; oral intake with a gastrostomy tube in place is started on day 4 after surgery
2. Group B: oral food is given the first day after surgery. No parenteral nutrition. Saline solution for volume substitution

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Occurrence of postoperative complications according to the Dindo-Clavien classification with particular respect for infections. Measured within the first 30 days after surgery

Key secondary outcome(s))
1. Recovery of bowel function (flatulence, passage of stool, nausea, vomiting)
2. Length of postoperative hospital stay
3. Nutritional biochemical variables
3.1. Serum albumin
3.2. Prealbumin
3.3. Total protein

Measured by questionnaire and blood samples on postoperative day 1, 3, 7, 10, 14 and 30 days after surgery.

Completion date
01/03/2012

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Consecutive series of 198 patients with invasive bladder cancer scheduled for cystectomy and extended pelvic lymph node dissection
2. Age >18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age <18y
2. Pregnancy
3. No informed consent available
4. Previous radiotherapy to the pelvis
5. Prior bowel surgery

Date of first enrolment
01/07/2010

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Inselspital
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) - Urology Department (Urologische Universitätsklinik)

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	01/03/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes