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

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

## Primary study design
Interventional

## Study design
Prospective single centre double blind randomised trial

## 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 |