

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

Submission date 25/06/2010	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/07/2010	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/07/2013	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet [in German]

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/07/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

198

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)

Sponsor details

Urology Department (Urologische Universitätsklinik)

Bern

Switzerland

3010

Sponsor type

Hospital/treatment centre

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

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	01/03/2013		Yes	No