

En-bloc resection for bladder cancer

Submission date 25/08/2015	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/09/2015	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/06/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Bladder cancer is one of the most common types of cancer. If the cancer is discovered early, the first step in the treatment is a procedure called a transurethral resection of the bladder tumor (TURB). In this procedure, the surgeon will locate the visible tumors and cut them away from the lining of the bladder. This is done by inserting a scope called a cystoscope into the bladder through the urethra (the tube that carries urine out of the body). Attached to this scope is a small, electrified loop of wire which is moved back and forth through the tumor to cut and remove the tissue. These tissue samples are then sent to a laboratory so that the tumor can be examined and graded. Although this procedure aims to remove the entire tumor and prevent them coming back (recurrence), the recurrence of tumors is common. A possible reason for this is that tumor cells are left behind (shedding) in this procedure, and are free to move to other places in the bladder to form new tumors. En-bloc resection is a technique where the surgeon removes the tumor in one piece. This could prevent the tumor cell shedding that may lead to tumor recurrence. The aim of this study is to find out whether en-bloc resection causes less tumor cell shedding than traditional TURB, and whether this reduces the overall risk of recurrence. The study also aims to find out if the tissue samples from en-bloc resection can help the pathologists in the laboratory in their analysis.

Who can participate?

Adults with newly diagnosed bladder cancer, with one to three bladder tumors between 1 and 3.5 cm in diameter.

What does the study involve?

Participants are randomly allocated into two groups. The first group are treated with the transurethral en-bloc resection of the bladder tumor (TUEBR) procedure, and the second group are treated with the conventional transurethral resection of the bladder tumor (TURB) procedure.

What are the possible benefits and risks of participating?

There are no known benefits or risks with the use of en-bloc resection compared to conventional TURB.

Where is the study run from?

1. Department of Urology, Skåne University Hospital (Sweden)
2. Department of Surgery, Urological section, Uddevalla Hospital (Sweden)

When is the study starting and how long is it expected to run for?

June 2013 to May 2020

Who is funding the study?

Research Council (Vetenskapsrådet) (Sweden)

Who is the main contact?

Dr Oliver Patschan

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Dnr 2013/23

Study information

Scientific Title

Prospective randomised trial comparing transurethral en-bloc resection (TUEBR) with conventional transurethral resection (TURB) for bladder cancer

Study objectives

This study aims to investigate whether en-bloc resection of newly diagnosed bladder cancer tumors might lead to less tumor cell implantation in the bladder than conventional TURB. This in turn might translate into a reduced frequency of recurrent tumors. En-bloc resection might also lead to more.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regionala Etikprövningsnämnd (Sweden), 05/02/2013, ref: 2013/23

Study design

Multi-centre prospective randomised controlled 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 the contact details below to request a patient information sheet (only available in Swedish).

Health condition(s) or problem(s) studied

Newly diagnosed bladder cancer (ICD10: C67.9)

Interventions

Participants are randomly allocated into the control group or the intervention group. The intervention group will undergo transurethral en-bloc resection of the bladder tumor (TUEBR), and the control group will undergo conventional transurethral resection of the bladder tumor (TURB).

For all patients: Follow up with cytology 4 weeks after operation. Cystoscopy and cytology 3, 6, 12, 18, 24, 36 months after operation, accordingly to our standard program.

Intervention Type

Procedure/Surgery

Primary outcome measure

Recurrence-free survival (RFS). For primary endpoint (recurrence) the time from operation to biopsy date, confirming the recurrence, is measured.

Secondary outcome measures

1. Interobserver variability of pathological stage. The histological slides from the primary operation are sent to 5 pathologists at the end of study. The tumorstage (Ta/T1/T2/Tis) is noted and the interobserver variability between groups is measured 3, 6, 12, 18, 24, 36 months after operation.
2. Urinary cytology after resection (normal, atypic or malign) is measured 3, 6, 12, 18, 24, 36 months after operation. An additional follow up with cytology will be 4 weeks after operation

Overall study start date

01/01/2013

Completion date

30/05/2022

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Newly diagnosed, suspected bladder cancer
2. Age 18 years or over
3. 1-3 bladder tumors
4. Tumor diameter between 1 and 3.5 cm

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

250

Total final enrolment

16

Key exclusion criteria

1. More than 3 tumors
2. Tumors larger than 3.5 cm
3. Solid tumors
4. Tumors with a large tumor base
5. Tumors in bladder diverticula

Date of first enrolment

01/06/2013

Date of final enrolment

30/05/2020

Locations

Countries of recruitment

Sweden

Study participating centre**Department of Urology**

Skåne University Hospital

Lund University

Jan Waldenströms gata 5

Malmö

Sweden

20502

Study participating centre**Department of Surgery, Urological section**

Urological Section

Department of Surgery

Uddevalla Hospital

Fjällvägen 9

Uddevalla

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Sponsor information

Organisation

Skåne University Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.enblocstudy.weebly.com>

ROR

<https://ror.org/02z31g829>

Funder(s)

Funder type

Not defined

Funder Name

Research Council (Vetenskapsrådet)

Alternative Name(s)

Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Results and Publications

Publication and dissemination plan

Publication will be done on congresses (EAU, DGU, SUF) and hopefully in higher impact journals, since it is a prospective clinical trial. By now, it is extremely difficult to foresee the pace of the recruiting process, but I think it is realistic to publish preliminary data in 2017.

Intention to publish date

01/06/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration