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En-bloc resection for bladder cancer

Submission date 25/08/2015	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/09/2015	**Overall study status** Stopped	
Last Edited 19/06/2023	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Bladder cancer is one of the most common types of cancer. If the cancer if 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

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Malmö
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Study participating centre
Department of Surgery, Urological section
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Sponsor information

Organisation
Skåne University Hospital

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration