ISRCTN80990426 https://doi.org/10.1186/ISRCTN80990426

Assessing the safety and effectiveness of a biopsy instrument when sampling tumours in the urinary bladder

Submission date
30/07/2020

Recruitment status
Recruiting

Registration date
10/09/2020

Overall study status
Ongoing

Last Edited
19/12/2024

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Muscle-invasive bladder cancer is cancer that has spread into the muscle wall of the bladder. Treatment is based on taking a biopsy (sample) of the tumor. Today a biopsy is retrieved by a surgical procedure called transurethral resection under anesthetic before treatment with either neoadjuvant chemotherapy (drug treatment) and cystectomy (removal of the bladder) or cystectomy only. The aim of this study is to investigate a new biopsy device (Urodrill) for diagnosing muscle-invasive bladder cancer under local anesthetic.

Who can participate?
Patients aged 18 and over with suspected muscle-invasive bladder cancer

What does the study involve?
Participants are randomly allocated to undergo either standard transurethral resection or an endoscopic biopsy under local anesthetic with the Urodrill instrument.

What are the possible benefits and risks of participating?
The benefit from participating is a chance to avoid a transurethral resection of the bladder tumor under anesthetic and instead have a local anesthetic procedure in the outpatient clinic. The risks are related to biopsying the tumor in the conventional and experimental group mainly relating to bleeding after the procedure and perforation.

Where is the study run from?
Skåne University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
November 2019 to June 2026

Who is funding the study?
Skåne Region Health Care Fund for Development and Innovation (Sweden)

Who is the main contact?
Prof. Fredrik Liedberg
fredrik.liedberg@med.lu.se

Contact information

Type(s)
Scientific

Contact name
Prof Fredrik Liedberg

ORCID ID
http://orcid.org/0000-0001-8193-0370

Contact details
Department of Urology
Lund University
Skåne University Hospital
Jan Waldenströmsgata 5
Malmö
Sweden
SE-205 02
+46 (0)40 33 19 41
fredrik.liedberg@med.lu.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CIV-20-05-032908

Study information

Scientific Title
Safety and efficacy of the EndoDrill® Uro X biopsy instrument when sampling tumours in the urinary bladder

Acronym
Urodrill study

Study objectives

Time from radiological suspicion to start of definitive treatment for muscle-invasive bladder cancer can be decreased by using the Urodrill pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/03/2020, National Ethical Committee (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: 2019-06537

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available

Health condition(s) or problem(s) studied
Bladder cancer

Interventions
Method of randomisation: closed envelopes
Conventional arm: standard transurethral resection
Experimental arm: endoscopic biopsy under local anesthesia with the Urodrill instrument

Intervention Type
Procedure/Surgery

Primary outcome measure
Time from radiological suspicion of MIBC to start of definitive treatment for MIBC (neoadjuvant chemotherapy and/or cystectomy): measured using prospective registration at day for radiological report stating suspicion of MIBC to starting day of neoadjuvant chemotherapy, or cystectomy for those operated without neoadjuvant chemotherapy by prospective registration

Secondary outcome measures
1. Complications from the EndoDrill biopsy procedure assessed by a structured telephone interview 2 weeks after the procedure
2. Proportion of patients with MIBC that the EndoDrill® Uro X -instrument failed to detect, but diagnosed with ordinary TURBT, measured using pathology at [at secondary procedure with TURBT for those in the experimental arm without verification of MIBC and with MIBC verified by

TURBT
3. Proportion of patients with successful molecular classification based on RNA sequencing performed in real time with 6 weeks of sampling in both arms
4. Cancer-specific survival (CSS) measured using chart review at 24 months after initiating definitive treatment for MIBC
5. Overall proportion of patients who correctly followed the protocol and were staged as MIBC in the intervention arm, measured using chart review within 3 months of inclusion
6. Cost-effectiveness based on EQ5D5L at baseline and 2 weeks
7. Quality of life measured using FACT-G questionnaire preoperatively and FACT-VCI at 12 months
8. Adverse events assessed during a phone interview by a research nurse 2 weeks after the procedures
9. Sensitivity and specificity for CT-urography and MRI respectively to accurately determine muscle-invasive bladder cancer compared to the outcome of the combined measure of biopsy and cystectomy specimen, measured using sensitivity calculations compared to pathology within 3 months of inclusion

Overall study start date
01/11/2019

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Provision of written informed consent
2. ≥18 years of age
3. Patients attending participating urology departments for haematuria investigation and CT-urography suspicious of muscle-invasive bladder cancer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
74

Key exclusion criteria
1. Patients unable or unwilling to undergo EndoDrill biopsy
2. Bleeding diathesis prohibiting EndoDrill biopsies
3. Ongoing immunosuppression (except corticosteroids in moderate doses, less than 10 mg

prednisolone or equivalent daily)
4. Patients not suitable/fit for radical treatment for MIBC
5. Pregnancy

Date of first enrolment
01/10/2020

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Skånes Universitetssjukhus
Department of Urology
Jan Waldenströms gata 7
Malmö
Sweden
205 02

Sponsor information

Organisation
Skåne University Hospital

Sponsor details
Department of Urology
Jan Waldenströmsgata 5
Malmö
Sweden
20502
+46 (0)40 33 10 00
fredrik.liedberg@med.lu.se

Sponsor type
Hospital/treatment centre

Website
http://www.skane.se/sv/Webbplatser/Skanes-universitetssjukhus/

ROR
https://ror.org/02z31g829

Funder(s)

Funder type
Government

Funder Name
Skåne Region Health Care Fund for Development and Innovation

Results and Publications

Publication and dissemination plan
Planned publication in a scientific peer-reviewed journal. The protocol and statistical analysis plan will not be publically available. The protocol has been finalised but nothing is publically available due to protection of the biopsy device.

Intention to publish date
31/05/2027

Individual participant data (IPD) sharing plan
The datasets generated in the present study will not be stored in a publically available repository due to the small study size and mainly descriptive data.

IPD sharing plan summary
Not expected to be made available