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Less intense follow-up in patients with intermediate-risk non-muscle invasive bladder cancer

Submission date 18/04/2024	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/05/2024	**Overall study status** Ongoing	
Last Edited 06/02/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
To prospectively investigate if a less intense follow-up schedule during the first 24 months for patients with primary or recurrent intermediate risk non-muscle invasive bladder cancer (NMIBC) after a negative first cystoscopy after transurethral resection of bladder (TURB) and adjuvant instillations have non-inferior oncologic outcomes defined as a proportion of patients with maximal diameter above 12 mm at recurrence. Additionally, the study aims to investigate if point-of-care use of urine tests in the de-escalated intervention arm is of value in this context.

Who can participate?
Patients with primary or recurrent intermediate-risk NMIBC

What does the study involve?
The study tests if it is safe to follow patients with NMIBC with less frequent endoscopic controls where we patients are allocated to a less intense follow-up protocol compared to the current standard which is every six months.

What are the possible benefits and risks of participating?
The benefit of participating is a 50% chance of having two instead of four cystoscopies during 2 years of observation of the disease.

The risks are related to slightly larger tumours at detection in the intervention group with less intense follow-up, although this will not affect the disease course over time.

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

When is the study starting and how long is it expected to run for?
December 2023 to February 2029

Who is funding the study?
Skåne University Hospital (Sweden)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
De-eScalated Follow-up in Intermediate-Risk NMIBC Gain Resources – a prospective ranDomized trial

Acronym
SIGRID

Study objectives
Less intense follow-up is non-inferior to the current guideline recommendations.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/03/2024, The Swedish Ethical Review Authority (Box 2110, Uppsala, SE-75002, Sweden; +46-10-475 08 00; registrator@etikprovning.se), ref: Dnr 2024-00076-01

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

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

Interventions
The study involves patients with intermediate-risk non-muscle invasive bladder cancer with normal first follow-up cystoscopy. The intervention is de-escalated follow-up, to decrease the burden of follow-up for patients and healthcare. Randomisation will be performed in RedCap.

Intervention Type
Procedure/Surgery

Primary outcome measure
The proportion of patients with a recurrent tumour above 12 mm measured using endoscopy in mm in relation biopsy forceps at 6, 12, 18 and 24 months

Secondary outcome measures
1. Health-related quality of life (HRQoL) measured using the EORTC Core Quality of Life questionnaire (EORTC QLQ-C30)-non-muscle-invasive bladder cancer 24 (NMIBC24) at 12 and 24 months
2. Incremental cost-effectiveness ratio (ICER) = total cost divided by gain in quality-adjusted life years (QALYs) for the less intense follow-up schedule measured using the EQ-5D-5L at 12 and 24 months
3. Proportion positive urine test at least one visit before recurrence measured using a tumour test applied on urine samples at 6, 12, 18 and 24 months
4. Rate of recurrence measured in medical record using the proportion with recurrent disease at

6, 12, 18 and 24 months
5. Rate of progression measured using a pathological assessment of recurrent tumours at 6, 12, 18 and 24 months
6. Number of cystoscopies examinations recorded in medical notes at 24 months

Overall study start date
02/12/2023

Completion date
01/02/2029

Eligibility

Key inclusion criteria
Primary or recurrent intermediate risk NMIBC

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Undergoing treatment for any other active malignancy
2. Previous pelvic radiotherapy
3. Pregnancy

Date of first enrolment
01/09/2025

Date of final enrolment
01/02/2028

Locations

Countries of recruitment
Sweden

Study participating centre
Skåne University Hospital, Dept. of Urology
Jan Waldenströmsgata 5
Malmö

Sweden
SE-205 02

Sponsor information

Organisation
Skåne University Hospital

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Sponsor type
Hospital/treatment centre

Website
https://vard.skane.se/skanes-universitetssjukhus-sus/

ROR
https://ror.org/02z31g829

Funder(s)

Funder type
University/education

Funder Name
Skånes universitetssjukhus

Alternative Name(s)
Skåne University Hospital, SUS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Sweden

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/02/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available