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Nurse-led hematuria (blood in urine) clinic – a prospective trial

Submission date	Recruitment status	[_] Prospectively registered
04/01/2023	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/12/2024	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
We want to study how well a new test for bladder cancer (the IB-test) works when used by nurses to quickly check for bladder cancer in people who have blood in their urine (hematuria). We also want to see if using nurses to do this test instead of doctors can save time and money. We will study this in women who are 50 or older and have blood in their urine in two different hospitals. We will also look at how well the test works and the cost of using it.

Who can participate?
All females above 50 years of age subject to investigation for visible hematuria in two hospitals.

What does the study involve?
Patients attending different centres will either undergo standardized care pathways or the nurse-led rapid access clinic and the use of diagnostic test (IB-test). Follow-up is for a minimum of 3 months.

What are the possible benefits and risks of participating?
No risks, but a possible benefit from earlier cystoscopy compared to urologist-led outpatient clinic examination.

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

When is the study starting and how long is it expected to run for?
October 2022 to June 2026

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

Who is the main contact?
Prof. Liedberg, anki.rosberg@med.lu.se

Contact information

Type(s)
Principal Investigator

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Prof Fredrik Liedberg

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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
CYstoskopi av kontaktsjuksköterska vid utredning för SynligT blod i urinEn hos kvinnoR – CYSTER-studien

Acronym
CYSTER

Study objectives
Shortened time to bladder cancer diagnosis in a nurse-led rapid access clinic compared to standardized care pathways for females with visible hematuria.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/12/2022, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se): ref: Dnr 2022-06049-01

Study design
Prospective interventional cluster crossover

Primary study design
Interventional

Secondary study design
Other cluster crossover design

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Macroscopic hematuria

Interventions
Intervention clusters: nurse-led rapid access clinic and the use of diagnostic test (IB-test).
Control clusters: standardized care pathways

Patients are included prior to diagnostic cystoscopy for macroscopic hematuria. The total duration of follow-up is until study closure with minimum of 3 months of follow-up to have full information on all outcomes related to the macroscopic hematuria evaluation.

Intervention Type
Other

Primary outcome measure
Time from hematuria to cystoscopy/bladder cancer diagnosis measured using patient records.

Secondary outcome measures
1. Patient reported experience measures (PREM): urography or cystoscopy PREM - Validated national questionnaire for patient-reported outcomes - filled in by patient after cystoscopy
2. Cost effectiveness measured using EQ-5D-5L and direct costs extracted from patient charts at the end of the study
3. Sensitivity and specificity for the IB-test to detect bladder cancer measured by comparing the IB test result to the actual outcome (positive or negative) at the end of the study

Overall study start date
26/10/2022

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Female
2. Hematuria referral
3. Aged 50 years or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Sex
Female

Target number of participants
800

Key exclusion criteria
1. Age below 50 years
2. Lack of informed consent

Date of first enrolment
25/01/2023

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Departments of Urology, Central Hospital Växjö
Strandvägen 8
Växjö
Sweden
35234

Study participating centre
Department of Urology, Skåne University Hospital
Jan Waldenströmsgata 5
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20502

Sponsor information

Organisation
Skåne University Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/02z31g829

Funder(s)

Funder type
Hospital/treatment centre

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
31/05/2027

Individual participant data (IPD) sharing plan
Not expected to be available due to confidentiality.

IPD sharing plan summary
Not expected to be made available