

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

Submission date 04/01/2023	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/02/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/12/2024	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

Prof Fredrik Liedberg

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information**Scientific Title**

Cystoskopi av kontaktsjuksköterska vid utredning för synlig 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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

Completion date

30/06/2026

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

50 years

Sex

Female

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

Malmö

Sweden

20502

Sponsor information

Organisation

Skåne University Hospital

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**Individual participant data (IPD) sharing plan**

Not expected to be available due to confidentiality.

IPD sharing plan summary

Not expected to be made available