

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

<b>Submission date</b> 04/01/2023	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/02/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/12/2024	<b>Condition category</b> 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](mailto: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 urin En 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](mailto: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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes