# 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

### Contact name

Prof Fredrik Liedberg

#### **ORCID ID**

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

# Contact details

Department of Urology Skåne University Hospital Jan Waldenströmsgata 5 Malmö Sweden 20502 +46 40-33 10 00 fredrik.liedberg@med.lu.se

# 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 Malmö Sweden 20502

# Sponsor information

# Organisation

Skåne University Hospital

# Sponsor details

Department of Urology Jan Waldenströmsgata 5 Malmö Sweden 20502 +46-40 333751 anki.rosberg@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

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