

SAGA-trial - investigating if intraoperative sterile water irrigation during an operation to remove the kidney due to cancer (nephroureterectomy for upper tract urothelial carcinoma) decreases the risk of tumor recurrence.

Submission date 30/08/2021	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/10/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/12/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Upper tract urothelial carcinoma is a type of cancer that affects the tubes connected to the kidney. Nephroureterectomy is surgery to remove the affected area. There is a risk of tumor recurrence. We aim to investigate if sterile water irrigation of the area during surgery decreases that risk.

Who can participate?

Patients aged 18 years old or above with upper tract urothelial carcinoma treated by nephroureterectomy.

What does the study involve?

Participants will be randomly allocated to receive sterile water irrigation during surgery or surgery as usual. Patients will be followed up for 2 years.

What are the possible benefits and risks of participating?

There are no risks of participating, but a chance to decrease the risk of later intravesical tumor recurrence if the study hypothesis is correct.

Where is the study run from?

Skåne University Hospital (Sweden)

When is the study starting and how long is it expected to run for?

May 2021 to September 2027

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Fredrik Liedberg, fredrik.liedberg@med.lu.se

Contact information

Type(s)
Scientific

Contact name
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
Sterile water irrigation at nephroureterectomy for upper tract urothelial carcinoma: a study on the effect on bladder tumour recurrence

Acronym
SAGA-trial

Study objectives

Intraoperative bladder irrigation with sterile water at nephroureterectomy decreases risk of bladder tumour recurrence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/06/2021, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: EPM Dnr: 2021-02919

Study design

Prospective multicenter randomized study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Upper tract urothelial carcinoma

Interventions

Control arm = no additional treatment during nephroureterectomy

Intervention arm = sterile water irrigation during nephroureterectomy

Randomization by sealed envelopes

Follow up for 2 years

Intervention Type

Procedure/Surgery

Primary outcome measure

Bladder cancer recurrence measured by cystoscopy up to 2 years after the operation

Secondary outcome measures

1. Quality of life assessed by EORTC QLQ 30 NMIBC six weeks after nephroureterectomy
2. Bladder cancer progression free survival as assessed at end of 2 years
3. Quality of life measured using EQ-5D-5L at six weeks after nephroureterectomy

Overall study start date

01/05/2021

Completion date

15/09/2027

Eligibility

Key inclusion criteria

1. 18 years old or above
2. Upper tract urothelial carcinoma treated by nephroureterectomy.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Lack of informed consent
2. Below 18 years of age

Date of first enrolment

01/10/2021

Date of final enrolment

31/12/2026

Locations

Countries of recruitment

Sweden

Study participating centre

Helsingborg Hospital

Charlotte Yhlens gata 10

Helsingborg

Sweden

252 23

Study participating centre
Skåne University Hospital
Jan Waldenströmsgata 5
Malmö
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205 02

Sponsor information

Organisation
Skåne University Hospital

Sponsor details
Dept. of Urology
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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
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/01/2027

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		18/05/2021	01/09/2021	No	Yes