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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	Recruitment status	[ ] Prospectively registered
30/08/2021	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/10/2021	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/12/2024	Cancer	[ ] 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
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Additional identifiers

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

Primary study design
Interventional

Study design
Prospective multicenter randomized study

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
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252 23

Study participating centre
Skåne University Hospital
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205 02

Sponsor information

Organisation
Skåne University Hospital

ROR
https://ror.org/02z31g829

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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