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SIGYN trial - a randomized study comparing gemcitabine and mitomycin in intermediate-risk non-muscle-invasive bladder cancer

Submission date 23/12/2020	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/02/2021	**Overall study status** Ongoing	
Last Edited 24/01/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The bladder stores urine before it is passed out of the body. It is located in the front of the pelvis. It is made up of 3 layers – an inner lining, a muscle wall and a thin layer in between called 'connective tissue'. Bladder cancer is a growth of abnormal tissue that starts in the lining and can spread to the muscle wall. Nonmuscleinvasive bladder cancer (NMIBC) is cancer that has not grown into the muscle wall of the bladder.
A transurethral resection of bladder (TURB) is usually the first treatment for early bladder cancer. The surgeon removes the tumour in the bladder through the urethra. The urethra is the tube that carries urine from the bladder to the outside of the body.
Mitomycin is a chemotherapy drug used to treat different cancers. Gemcitabine is a type of chemotherapy drug.
The aim of this study is to compare the outcomes for gemcitabine compared to mitomycin.

Who can participate?
All individuals with intermediate risk NMIBC operated with radical TURB above the age of 18

What does the study involve?
Participants will be randomly allocated to receive gemcitabine and mitomycin or mitomycin alone weekly for 6 weeks. Participants will be followed up for 24 months.

What are the possible benefits and risks of participating?
Benefits: Potentially better and less toxic treatment for those who receive gemcitabine.
Risks: Chemical cystitis, with the hypothesis that gemcitabine is less toxic than mitomycin.

Where is the study run from?
Eksjö Höglandssjukhuset (Sweden)

When is the study starting and how long is it expected to run for?
June 2020 to December 2026

Who is funding the study?
Cancerfonden (Swedish Cancer Society)

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

EudraCT/CTIS number
2020-001728-33

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Adjuvant instillations in intermediate risk NMIBC: A Study comparIng Gemcitabine and MitomYciN (SIGYN-trial)

Acronym
SIGYN

Study objectives
In patients with intermediate risk non-muscle invasive bladder cancer treated with serial adjuvant chemotherapy instillations, gemcitabine improves local recurrence free survival compared to mitomycin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2020, Etikprövningsmyndigheten (Swedish Ethical Review Authority, Box 2110, 750 02 Uppsala, Sweden; +46 10 475 08 00; registrator@etikprovning.se), ref: 2020-02143

Study design
Prospective randomized open study design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Intermediate-risk non-muscle-invasive bladder cancer

Interventions
Prospectively randomized study to evaluate local cancer free survival in intermediate risk non-muscle invasive bladder cancer treated with adjuvant gemcitabine compared to current treatment standard which is mitomycin once weekly for six weeks.

Participants will be randomised (1:1) using an online tool to:
1. Gemcitabine 100 mg once weekly for 6 weeks
2. Mitomycin 40 mg once weekly for 6 weeks

Follow-up of all patients continues until the last patient has been followed for 24 months

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gemcitabine, mitomycin

Primary outcome measure
Local recurrence free survival assessed at cystoscopy controls at 3, 6, 12, 18, 24 months

Secondary outcome measures
Measured at baseline and 8 weeks:
1. Treatment related side effects assessed by national questionnaire
2. Health-related quality of life (EORTC-QLQ30+NMIBC24)
3. Health economy progression free survival (EQ-5D-5L)
4. Adverse events (patient records)

Overall study start date
30/06/2020

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Intermediate risk non-muscle invasive bladder cancer
3. Radically performed transurethral resection of the tumour
4. Written and verbal consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
340

Key exclusion criteria
1. Age below 18
2. Pregnancy
3. Allergy to gemcitabine or mitomycin
4. Chronic catheter
5. Severe incontinence

Date of first enrolment

30/06/2021

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Eksjö Höglandssjukhuset
Västanågatan 9
Eksjö
Sweden
575 33

Sponsor information

Organisation
Skåne University Hospital

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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

Charity

Funder Name
Cancerfonden

Alternative Name(s)
Swedish Cancer Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality

IPD sharing plan summary
Not expected to be made available