

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/02/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/01/2025	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

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
Prof Fredrik Liedberg

ORCID ID
<https://orcid.org/0000-0001-8193-0370>

Contact details
Dept. of Urology
Skåne university Hospital
Jan Waldenströmsgata 5
Malmö
Sweden
205 02
+46 40 33 19 41
fredrik.liedberg@med.lu.se

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 Högländssjukhuset

Västanågatan 9

Eksjö

Sweden

575 33

Sponsor information

Organisation

Skåne University Hospital

Sponsor details

Department of Urology

Jan Waldenströmsgata 7

Malmö

Sweden

205 02

+46 (0)40 33 10 00

fredrik.liedberg@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

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