

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

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
23/12/2020	Recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
10/02/2021	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
04/02/2026	Cancer	<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

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### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)  
2020-001728-33

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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](mailto:registrator@etikprovning.se)), ref: 2020-02143

### **Study design**

Prospective randomized open study design

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

110 years

**Sex**

All

**Total final enrolment**

0

**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

### 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

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes