

# Treatment of bladder cancer with gemcitabine and docetaxel (for people not responding to Bacillus Calmette-Guerin (BCG) treatment)

<b>Submission date</b> 30/01/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/02/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/06/2025	<b>Condition category</b> 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

Bladder cancer is a type of cancer that starts in the bladder, a muscular organ in the lower abdomen that stores urine.

Bacillus Calmette-Guerin (BCG) treatment is a type of immunotherapy used to treat bladder cancer by boosting the body's natural defence system. It is instilled directly into the bladder to fight the cancer cells.

When people with bladder cancer do not respond to or cannot tolerate BCG treatment, and cannot have a radical cystectomy due to health problems or their own decision, there are no proven treatment options. Doctors recommend these patients take part in clinical trials. A type of treatment using gemcitabine and docetaxel has been reported to have good results with limited side effects in some studies, but it has not been tested in a large, controlled trial. This study will examine the effectiveness and side effects of the gemcitabine and docetabine treatment, as well as its cost and whether the type of bladder cancer cells predicts how well the treatment works.

### Who can participate?

Patients with non-BCG-responsive bladder cancer not suitable for surgery to remove the bladder.

### What does the study involve?

Patients are treated with gemcitabine and docetaxel including six weekly induction courses and maintenance installations once a month for nine months. Follow-up is for 24 months.

### What are the possible benefits and risks of participating?

Patients participating will receive a second-line treatment that seems very promising. The same risks as for all intravesical treatments with chemical cystitis are the main side-effects that are anticipated.

### Where is the study run from?

Skåne University Hospital (Sweden)

When is the study starting and how long is it expected to run for?  
January 2023 to March 2029

Who is funding the study?  
Skåne University Hospital (Sweden)

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

## Contact information

### Type(s)

Principal Investigator

### Contact name

Prof Fredrik Liedberg

### ORCID ID

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

### Contact details

Skåne University Hospital  
Department of Urology  
Jan Waldenströmsgata 5  
Malmö  
Sweden  
SE-205 02  
+46 40 33 10 00  
fredrik.liedberg@med.lu.se

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Sequential instillations with gEmCitaBin and dOcetaxel for BCG-unrespoNsive and BCG-intolerant blaDdercancer – SECOND-trial.

### Acronym

SECOND-trial

### **Study objectives**

Sequential instillations with gem/doc for BCG-unresponsive Non-muscle-invasive Bladder Cancer (NMIBC) can be administered with reasonable toxicity and recurrence-free survival in patients not suitable for radical cystectomy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 29/01/2023, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: EPM 2022-06399-01.

### **Study design**

Prospective interventional single-arm phase II trial

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

Hospital

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

Treatment

### **Participant information sheet**

See study outputs table

### **Health condition(s) or problem(s) studied**

Non-muscle-invasive bladder cancer

### **Interventions**

The prospective trial investigates intravesical administration of sequential gemcitabine and docetaxel (gem/doc) including six weekly induction courses and maintenance installations once a month for 9 months to assess RFS and complete response at 12 and 24 months, as well as side effects, health-related quality of life and health economic evaluation.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Gemcitabine, docetaxel

**Primary outcome measure**

1. Complete remission (CR) at 24 months measured using patient records
2. Recurrence-Free Survival (RFS) and Progression-Free Survival (PFS) assessed by cystoscopies and voided urinary cytology during follow-up.

**Secondary outcome measures**

1. Health-related quality of life is assessed by EORTC-QLQ30-NMIBC24 before induction treatment, four weeks after induction chemotherapy at 10 weeks and four weeks after completion of all 9 maintenance installations.
2. Side-effects are monitored before each installation by the national side-effect questionnaire.
3. Health economic assessment is performed by applying data from the EQ-5D-5L and EORTC-QLQ30-NMIBC24 questionnaires at the end of the study

**Overall study start date**

29/01/2023

**Completion date**

01/03/2029

## Eligibility

**Key inclusion criteria**

1. BCG-unresponsive NMIBC
2. BCG-intolerant NMIBC
3. BCG-recurrent NMIBC

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. Allergy to either gem or doc
2. Chronic urinary catheter
3. Severe incontinence affecting possibilities to retain intravesical instillations

**Date of first enrolment**

01/03/2023

**Date of final enrolment**

01/03/2027

## Locations

**Countries of recruitment**

Sweden

**Study participating centre****Skåne University Hospital**

Department of Urology

Jan Waldenströmsgata 5

Malmö

Sweden

205 02

**Study participating centre****Landskrona Hospital**

Vattenverksallén 15

Landskrona

Sweden

SE-261 36

**Study participating centre****Helsingborg County Hospital**

Charlotte Yhlens gata 10

Helsingborg

Sweden

SE-252 23

**Study participating centre****Ängelholm Hospital**

Landshövdingevägen 7E

Ängelholm

Sweden

SE-262 52

**Study participating centre****Växjö County Hospital**

Strandvägen 8

Växjö

Sweden

SE-352 34

**Study participating centre**  
**Ljungby Hospital**  
Kyrkogatan 2  
Ljungby  
Sweden  
SE-341 35

**Study participating centre**  
**Eksjö Hospital**  
Västanågatan 9  
Eksjö  
Sweden  
SE-575 81

**Study participating centre**  
**Jönköping Hospital**  
Sjukhusgatan  
Jönköping  
Sweden  
SE-553 05

**Study participating centre**  
**Värnamo Hospital**  
Doktorsgatan 5  
Värnamo  
Sweden  
SE-331 52

## **Sponsor information**

**Organisation**  
Skåne University Hospital

**Sponsor details**  
Department of Urology,  
Jan Waldenströmsgata 5  
Malmö  
Sweden  
SE-20502  
+46 40 33 10 00  
jenny.hellfalk@skane.se

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.skane.se/sv/Webbplatser/Skanes-universitetssjukhus/>

**ROR**

<https://ror.org/02z31g829>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Skånes universitetssjukhus

**Alternative Name(s)**

Skåne University Hospital, SUS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Sweden

## **Results and Publications**

**Publication and dissemination plan**

Peer-reviewed medical journal

**Intention to publish date**

01/03/2029

**Individual participant data (IPD) sharing plan**

Available on request.

[fredrik.liedberg@med.lu.se](mailto:fredrik.liedberg@med.lu.se)

**IPD sharing plan summary**

Available on request

**Study outputs**

**Output type**

[Participant information sheet](#)

**Details**

**Date created**

**Date added**

31/01/2023

**Peer reviewed?**

No

**Patient-facing?**

Yes