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

Submission date	Recruitment status Recruiting	[X] Prospectively registered		
30/01/2023		☐ Protocol		
Registration date	Overall study status Ongoing Condition category Cancer	Statistical analysis plan		
15/02/2023		Results		
Last Edited		Individual participant data		
09/06/2025		[X] 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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), ref: EPM 2022-06399-01.

Study design

Prospective interventional single-arm phase II trial

Primary study design

Interventional

Study type(s)

Treatment

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(s)

- 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.

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

Individual participant data (IPD) sharing plan

Available on request. fredrik.liedberg@med.lu.se

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			31/01/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes