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

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

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), 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

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