Evaluation of treatment of local bladder cancer with Bacille Calmette-Guérin (BCG). Is treatment follow up in the outpatient department just as good as follow up in the operating theatre?

Submission date	Recruitment status	Prospectively registered
09/09/2011	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
20/01/2012	Completed	Results
Last Edited	Condition category	[] Individual participant data
20/01/2012	Cancer	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

UOF no 3

Study information

Scientific Title

Detection rate of carcinoma in situ (CIS) after intravesical Bacille Calmette-Guérin (BCG) in fluorescence guided flexible cystoscopy in the outpatient department (OPD) compared to fluorescence guided cystoscopy in rigid cystoscopes in the operating theatre (OT).

Acronym

UOF3

Study objectives

Fluorescence guided cystoscopy and biopsy performed in the OPD is just as good as fluorescence guided cystoscopy and biopsy in rigid scopes in the operating theatre to evaluate the efficacy of intra vesical BCG therapy of carcinoma in situ.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single center study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Cancer of the urinary bladder - carcinoma of the bladder - CIS

Interventions

Fluorescence guided cystoscopy and biopsy in rigid scopes in the operating theatre and in flexible cystoscopes in the outpatient department

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Histological diagnosis from evaluation of bladder biopsy

Key secondary outcome(s))

Quality of life and pain in relation to test procedures

Completion date

Eligibility

Key inclusion criteria

Patients who have had 6 weekly BCG bladder instillations as treatment of primary or secondary carcinoma in situ of the bladder.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients who do not understand Danish or who the investigators do not find able to fulfil the study

Date of first enrolment

01/12/2011

Date of final enrolment

30/04/2013

Locations

Countries of recruitment

Denmark

Study participating centre Department of Urology

Copenhagen Denmark DK-2000

Sponsor information

Organisation

Frederiksberg Hospital (Denmark)

ROR

https://ror.org/00d264c35

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Frederiksberg Hospital, Copenhagen University (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes