ISRCTN48222814 https://doi.org/10.1186/ISRCTN48222814

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
09/09/2011

Recruitment status
No longer recruiting

Registration date
20/01/2012

Overall study status
Completed

Last Edited
20/01/2012

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Histological diagnosis from evaluation of bladder biopsy

Secondary outcome measures
Quality of life and pain in relation to test procedures

Overall study start date
01/12/2011

Completion date
30/04/2013

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

Age group
Adult

Sex
Both

Target number of participants
30

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)

Sponsor details
c/o Dr Gregers G Hermann
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Sponsor type
Hospital/treatment centre

Website
http://www.frederiksberghospital.dk/

ROR
https://ror.org/00d264c35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Frederiksberg Hospital, Copenhagen University (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration