

# 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?

<b>Submission date</b> 09/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/01/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**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

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

### 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