

# PhotoDynamic Diagnosis (PDD) and results of biopsies in flexible cystoscopy of bladder tumour patients in an Out-Patient Department set up

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/11/2009	<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

### Contact name

Dr Gregers G Hermann

### Contact details

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Denmark  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

PhotoDynamic Diagnosis (PDD) and results of biopsies in flexible cystoscopy of bladder tumour patients in an Out-Patient Department set up: a quality assurance study

### Acronym

PDD in OPD

### Study objectives

The study was carried out to develop a method for photodynamic diagnosis (PDD) and bladder biopsies in flexible cystoscopes in the out-patient department (OPD). PDD in the operating theatre and cystoscopy and biopsy using flexible cystoscopes are routine methods in urology departments. The issue was to evaluate them for use in the OPD and to see the quality of biopsies obtained through the scopes. The examinations were performed to see whether we got a usable procedure for a subsequent study comparing the method in OPD and in the operating theatre during admittance to the ward.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The Danish Medicines Agency (Danish FDA) and the Ethical Committee in Copenhagen feel that there isn't a need to evaluate this study as the methods are commonly used.

### Study design

Quality assurance, non-randomised single arm pilot study

### Primary study design

Interventional

### Secondary study design

Non randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### 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

Non-muscle invasive bladder tumour

### Interventions

Instillation of 50 cc fluorescent material in to the bladder 1 hour before cystoscopy. The instillation gives no side effects. Each treatment last for 15 - 30 minutes and there is no follow-up.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Acceptable view in the bladder, measured immediately during the cystoscopy

**Secondary outcome measures**

Sufficient biopsy information for a valid diagnosis, assessed a few days after cystoscopy where the pathologist give the histological description of the biopsy

**Overall study start date**

09/04/2008

**Completion date**

01/04/2009

## Eligibility

**Key inclusion criteria**

1. Patients booked for flexible cystoscopy due to follow up of recurrent bladder tumour according to the guidelines of the ward
2. Aged 54 - 91 years, either sex

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

37

**Key exclusion criteria**

1. Patients refuse
2. Non-recurrent bladder tumour disease
3. Pregnancy
4. Aged less than 18 years

**Date of first enrolment**

09/04/2008

**Date of final enrolment**

01/04/2009

## **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 Consultant Urologist Gregers G Hermann

Department of Urology

Copenhagen University

Ndr. Fasanvej 57

Frederiksberg

Copenhagen

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DK-2700

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.frederiksberghospital.dk/menu/Afdelinger/Urologisk+linik/UrologiskKlinik.htm>

**ROR**

<https://ror.org/00d264c35>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

The Foundation Juchum (Denmark) - provided financial support

**Funder Name**

Boemske Foundation (Denmark) - provided financial support

**Funder Name**

Karl Storz, Tuttlingen (Germany) - kindly delivered flexible cystoscope systems

**Funder Name**

Richard Wolf GmbH (Germany) - kindly delivered flexible cystoscope systems

## **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