

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

Submission date 02/07/2009	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/11/2009	Overall study status Completed	☐ Protocol
Last Edited 30/11/2009	Condition category Cancer	☐ 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

Method development II

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.

Primary study design

Interventional

Study design

Quality assurance, non-randomised single arm pilot study

Study type(s)

Treatment

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(s)

Acceptable view in the bladder, measured immediately during the cystoscopy

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration