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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 [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/11/2009	**Overall study status** Completed	
Last Edited 30/11/2009	**Condition category** Cancer	

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
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 evaulate this study as the methods are commonly used.

Study design
Quality assurance, non-randomised single arm pilot study

Primary study design
Interventional

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