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A longitudinal non-invasive study of changes in urinary bladder contractility secondary to benign prostatic hyperplasia.

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/06/2021	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.erasmusmc.nl/urologie/furore

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A300112

Study information

Scientific Title
A longitudinal non-invasive study of changes in urinary bladder contractility secondary to benign prostatic hyperplasia.

Study objectives
With increasing age the prostate enlarges. In response to the increasing resistance to urinary flow, the urinary bladder changes (compensation). At a later stage the bladder may decompensate which eventually makes emptying the bladder impossible (urinary retention).

During the compensation phase, pressures in the bladder may become excessive, leading to reflux of urine and kidney damage. Compensation and decompensation of the urinary bladder muscle are important issues in the decision to operate. These changes in function of the bladder muscle can be assessed by calculating its contractility from urodynamic measurements of pressure and flow-rate during voiding. Presently, such pressure measurements are invasive.

For this reason these measurements are not done as often as desirable and have also rarely been done in an epidemiological study. Therefore no reference data on the development of the contractility of the bladder muscle in response to prostatic enlargement is available and it is unknown if and when a certain degree of obstruction of the outflow tract will cause irreversible damage to the bladder wall muscle.

The sector Furore (Physics, function and reconstruction of the urinary tract) of the department Urology of the EMCR has developed a method to measure the urinary bladder pressure non-invasively. This method now makes it possible to acquire the necessary reference data in a non-invasive epidemiological study.

Aim:
To investigate the consequences of prostate hyperplasia on the bladder in the course of time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Longitudinal study

Primary study design
Observational

Secondary study design

Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Benign Prostatic Hyperplasia (BPH)

Interventions
Non-invasive measurement of the urinary bladder pressure.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The study is observational, there is no endpoint.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2001

Completion date
01/10/2009

Eligibility

Key inclusion criteria
1. Men aged 38 - 77 years
2. Mentally and physically able to complete a voiding diary and to visit the outpatient clinic
3. Written informed consent to participate in the trial

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
1020

Total final enrolment
1020

Key exclusion criteria
1. Unable to urinate in a standing position
2. Previous lower urinary tract surgery
3. Congenital disease of the lower urinary tract
4. Use of medication or other interventions for lower urinary tract symptoms
5. Other diseases that could alter urinary function (e.g., Parkinsons, Cerebrovascular Accident [CVA], Diabetes Mellitus [DM], kidney failure, bladder/prostate cancer, current urinary tract infection)
6. Heart failure
7. Voiding pattern at first visit incompatible with measurement technique, e.g., flow rate too low (less than 6 ml/s), interrupted voiding, straining
8. Mentally or physically unable to complete a voiding diary and to visit the outpatient clinic
9. Use anticoagulants

Date of first enrolment
01/11/2001

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Head sector FURORE
Rotterdam
Netherlands
3000 DR

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Dr Molewaterplein 40/50
Rotterdam

Netherlands
3000 CA

Sponsor type
University/education

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
Dutch Kidney Foundation (Nierstichting Nederland) (The Netherlands)

Alternative Name(s)
Dutch Kidney Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
Erasmus University Rotterdam (The Netherlands) - Vereniging Trustfonds

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2014	10/06/2021	Yes	No