

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

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|----------------------------------------|--------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>20/12/2005   | <b>Recruitment status</b><br>No longer recruiting            | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>20/12/2005 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>10/06/2021       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                              | <input checked="" type="checkbox"/> Results          |
|                                        |                                                              | <input type="checkbox"/> Individual participant data |

## 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

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

**Primary study design**

Observational

**Study design**

Longitudinal study

**Study type(s)**

Treatment

**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(s)**

The study is observational, there is no endpoint.

**Key secondary outcome(s)**

No secondary outcome measures

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**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 FUIORE**

Rotterdam

Netherlands

3000 DR

## Sponsor information

**Organisation**

Erasmus Medical Centre (Netherlands)

**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

**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? |
|---------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |               | 01/01/2014   | 10/06/2021 | Yes            | No              |
| <a href="#">Study website</a>   | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |