

Waking up at night to urinate in patients with benign prostatic enlargement and the effects of drug treatment for night urination

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| Submission date 30/10/2018 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 12/11/2018 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 17/12/2018 | Condition category 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

Background and study aims

Nocturia - the need to get up in the middle of the night to urinate - is perceived as one of the most bothersome symptoms of all lower urinary tract symptoms by most men, especially older men. Frequent nocturia, can lead to a lack of sleep, a decline in energy and reduced quality of life. The causes of nocturia are varied, including urinary tract symptoms and benign prostatic enlargement, but also cardiovascular disease, diabetes, and other factors causing wakefulness and urination (such as anxiety and sleep disorder). This study aims to evaluate nocturia in patients with lower urinary tract symptoms and benign prostatic enlargement, along with looking at the effectiveness of drugs to treat nocturia.

Who can participate?

Men aged 50 or over with benign prostatic hyperplasia

What does the study involve?

Participants will be randomly allocated to receive either the study drug or a placebo (control). Those allocated to receive the study drug will receive 2 mg of tamsulosin to take once daily for 8 weeks, and participants in the control group will take the placebo once daily for 8 weeks. All participants will be asked to complete various questionnaires and tests, including PSA tests, urinalysis and uroflowmetry before and after taking the study drug or placebo.

What are the possible benefits and risks of participating?

Some patients with LUTS/BPH will benefit from the drug therapy as it may reduce nocturia and hence improve their quality of life.

There are no known risks to participants taking part in this study.

Where is the study run from?

Beijing Huairou Hospital (China)

When is the study starting and how long is it expected to run for?

November 2014 to February 2017

Who is funding the study?
Beijing Huairou Hospital (China)

Who is the main contact?
Prof. Yongguang Jiang
jyg_doctor@sina.com

Contact information

Type(s)
Scientific

Contact name
Prof Yongguang Jiang

Contact details
No.2, anzhen Road, Chaoyang district
beijing
China
100029
+861064412431
jyg_doctor@sina.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An evaluation of nocturia in patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia, and analysis of the curative effect after medical or placebo therapy for nocturia: a randomised placebo-controlled study

Study objectives
The improvement of nocturia in patients with α -adrenoceptor antagonist therapy will better than the placebo therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Interventional two-arm open randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Nocturia

Interventions

Participants will be randomly allocated to one of two groups. One group will receive an α -adrenoceptor antagonist (2 mg tamsulosin to be taken once daily orally) and the other will be the control group and will receive a placebo. Both groups will take their allocated drug for 8 weeks.

Participants will complete questionnaires relating to quality of life and prostate symptoms, along with frequency volume charts at the baseline and after taking the drug for 8 weeks. Participants will also complete PSA (prostate-specific antigen) tests, urinalysis, PV (prostate volume) test and uroflowmetry at the baseline and after 8 weeks. Factors such as disease, disease treatment, operation, drinking habits and smoking habits will be recorded at the baseline.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Tamsulosin

Primary outcome measure

The following are assessed at the baseline and after 8 weeks:

1. Symptoms of benign prostatic hyperplasia, assessed using the International Prostate Symptom Score (I-PSS)
2. Serum PSA levels, assessed using a serum PSA test
3. Prostate volume, assessed using a prostate ultrasound

4. A 3-day bladder diary is used to assess the following:

- 4.1. Nocturnal urine volume
- 4.2. Frequency of nocturia
- 4.3. Drinking water volume
- 4.4. Drinking water volume 4 hours before bedtime
- 4.5. Maximum urination volume
- 4.6. Morning urine volume

Secondary outcome measures

N/A

Overall study start date

01/11/2014

Completion date

01/02/2017

Eligibility

Key inclusion criteria

- 1. Aged at least 50 years
- 2. Diagnosed with benign prostatic hyperplasia
- 3. Male

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

88

Key exclusion criteria

- 1. Prostate cancer
- 2. PSA >10 ng/ml
- 3. Urinary tract infection
- 4. Disease of the nervous system
- 5. Urolithiasis
- 6. Medical therapy that could affect the function of urination
- 7. Prostatic surgery
- 8. Pelvic surgery

Date of first enrolment

01/01/2015

Date of final enrolment

31/05/2016

Locations

Countries of recruitment

China

Study participating centre

Bei Jing Huairou Hospital

No.9,yongyai north street,Huairou District

beijing

China

101400

Sponsor information

Organisation

Beijing Huairou Hospital

Sponsor details

No.9, yongyai north street, huairou district

Beijing

China

101400

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02jwb5s28>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Beijing Huairou Hospital

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal

Intention to publish date

01/05/2018

Individual participant data (IPD) sharing plan

The dataset used and/or analysed during the currently reliability study is available from the corresponding author, Yongguang Jiang, jyg_doctor@sina.com, on reasonable request. All participants submitted a signed informed consent form that included information about the purpose of the study, its procedures, the participants' rights and welfare, participants' protections and the collection of data for publication. Individual data (age, comorbidities, evaluation data of nocturia, data comparison between therapeutic interventions), will be shared starting on 01/01/2019 upon previous communication and solicitation by responsible study contact personnel, as indicated.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 13/12/2018 | | Yes | No |