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

Submission date
30/10/2018

Recruitment status
No longer recruiting

Registration date
12/11/2018

Overall study status
Completed

Last Edited
17/12/2018

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 symtoms 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 uroflowometry 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
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Contact information

Type(s)
Scientific

Contact name
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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)

The Ethics Committee of Beijing Huairou Hospital, 25/10/2014, Ref: BJHR20141020

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 uroflowometry 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