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Using a high-power thulium laser system in the operation to treat benign prostate hyperplasia

Submission date
25/02/2015

Recruitment status
No longer recruiting

Registration date
06/03/2015

Overall study status
Completed

Last Edited
11/05/2015

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
Benign prostate enlargement is a common disease in older men where a small gland called the prostate becomes enlarged, putting pressure on the bladder and the tube through which urine passes. This may cause difficulty starting urination, a frequent need to urinate, and difficulty fully emptying the bladder. Transurethral resection of the prostate (TURP) is a surgical procedure where an electric wire loop heated by radio waves is used to remove excess prostate tissue, reducing the pressure on your bladder. Prostate vaporization and enucleation (ThuVEP) is a new treatment option in which a laser is used to remove the excess tissue. The aim of this study is to find out whether ThuVEP is a safe and effective treatment for benign prostate enlargement.

Who can participate?
Men diagnosed with benign prostate enlargement.

What does the study involve?
We collected data from 29 patients who underwent ThuVEP and 30 patients who underwent TURP before the operation and at 3, 6, 9 and 12 months after the operation.

What are the possible benefits and risks of participating?
Both operations are widely used in clinical practice and may help with the patients' urination difficulties. There are no additional risks of participating.

Where is the study run from?
Taipei Veterans General Hospital (Taiwan).

When is the study starting and how long is it expected to run for?
From August 2010 to August 2013.

Who is funding the study?
Taipei Veterans General Hospital (Taiwan).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VGHIRB: 201007014IC

Study information

Scientific Title
Vapoenucleation of the prostate using a high-power thulium laser: a one-year follow-up study

Study objectives
Prostate vaporization and enucleation is a novel treatment option for bladder outlet obstruction caused by benign prostate enlargement. Using a high-power thulium laser to accomplish vapoenucleation of the prostate (ThuVEP) is safe and effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Taipei Veterans General Hospital, Taipei, Taiwan (VGHIRB) 201007014IC

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urinary frequency, nocturia, weak stream, or urine retention

Interventions
We prospectively collected and analyzed data from 29 patients who underwent vapoenucleation of the prostate (ThuVEP) between August 2010 and May 2012. The control group included 30 patients who underwent traditional transurethral resection of the prostate (TURP). Operative variables, patient profiles, preoperative and postoperative urine flow rates, prostate volume (measured using transrectal ultrasonography), and the international prostate symptom score (IPSS) were recorded and analyzed using a two-tailed Student’s t-test and analysis of variance.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Operative variables obtained before the operation
2. Patient profiles obtained before the operation
3. Urine flow rates obtained before the operation and at 3, 6, 9 and 12 months after the operation
4. Prostate volume (measured using transrectal ultrasonography) obtained before the operation and at 3, 6, 9 and 12 months after the operation
5. International prostate symptom score (IPSS) via questionnaires obtained before the operation and at 3, 6, 9 and 12 months after the operation

Secondary outcome measures
1. Urine flow rates obtained at 6, 9 and 12 months after the operation
2. Prostate volume (measured using transrectal ultrasonography) obtained at 6, 9 and 12 months after the operation
3. International prostate symptom score (IPSS) via questionnaires obtained at 6, 9 and 12 months after the operation

Overall study start date
01/08/2010

Completion date
01/08/2013

Eligibility

Key inclusion criteria
1. International prostate symptom score (IPSS) >7
2. Maximum urinary flow rate (Qmax) <15 mL/s
3. Normal level of age-specific prostate-specific antigen (PSA)
4. Patients with abnormal levels of age-specific PSA or positive findings on digital rectal examination underwent transrectal ultrasonography (TRUS)-guided biopsy to rule out prostate cancer. Ten patients underwent TRUS-guided biopsy before the operation

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
35

Key exclusion criteria
Prostate cancer

Date of first enrolment
01/08/2010

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Taiwan

Study participating centre
Taipei Veterans General Hospital
No.201, Sec. 2, Shipai Rd
Beitou District

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Sponsor information

Organisation
Taipei Veterans General Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03ymy8z76

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Taipei Veterans General Hospital (Taiwan)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/05/2015		Yes	No