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Comparative evaluation of the surgical outcome Thulium laser enucleation of the prostate

Submission date
18/05/2015

Recruitment status
No longer recruiting

Registration date
25/06/2015

Overall study status
Completed

Last Edited
26/02/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Benign prostatic hyperplasia is a condition affecting older men where the prostate becomes enlarged. This can cause difficulties in urination, a desire to urinate frequently and difficulty in fully emptying the bladder. It is usually treated by surgery which involves cutting away a section of the prostate gland in a procedure called transurethral resection of the prostate TURP). In this study, we are going to compare a new procedure, Thulium Laser Prostatectomy (ThuLEP) with the gold standard treatment, TURP, and a traditional treatment called Open Simple Prostatectomy (OSP).

Who can participate?
Participants that are eligible for surgical treatment of benign prostatic hyperplasia

What does the study involve?
All participants undergo an extensive evaluation before surgery which includes urodynamic study, evaluation of symptoms, quality of life and erectlie function. These are evaluated again in the follow-up period after surgery. Participants are randomised to either undergo ThuLEP or TURP surgery. Information on OSP cases are collected over a period of time.

What are the possible benefits and risks of participating?
The use of the currently most advanced 200W Thulium laser device (Revolix 200, Lisa laser products OHG, Katlenburg-Lindau, Germany) may prove of benefit for the patients.

Where is the study run from?
Department of Urology, University of Patras (Greece)

When is the study starting and how long is it expected to run for?
December 2013 to December 2016

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Professor Evangelos Liatsikos

Contact information

Type(s)
Public

Contact name
Dr Evangelos Liatsikos

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5921/19-3-2014

Study information

Scientific Title
Comparative evaluation of the surgical outcome Thulium laser (200W) enucleation of the prostate: Comparative assessment with transurethral resection of the prostate and open simple prostatectomy.

Study objectives
Improvement of symptoms, maximum flow and complication profile of the Thulium laser enucleation (ThuLEP) in comparison to the transurethral resectionof the prostate (TURP) and the open simple prostatectomy (OSP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific Board of University Hospital of Patras, Rion, Patras, Greece, 02/12/2013, ref: 5921/19-3-2014

Study design
Randomized comparison of surgical treatments for benign prostatic hyperplasia

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Benign prostatic hyperplasia, benign bladder outlet obstruction, urology

Interventions
1. Randomization arm 1: Thulium laser enucleation (ThuLEP)
2. Randomization arm 2: Transurethral Resection of the Prostate (TURP)
Prospective data collection of consecutive cases: Open Simple Prostatectomy (OSP)

Intervention Type
Device

Primary outcome measure
1. Symptoms (International Prostate Symptom Score, I-PSS), measured pre-operatively, at 1 month, at 3 months and at 12 months
2. Maximum flow rate: Urodynamic evaluation, measured pre-operatively and at 3 months
3. Time for catheter removal
4. Erectile function (International Index of Erectile Function Questionnaire, IIEF) at 1 month, 3 months and 12 months
5. Complications during first month after surgery and at 12 months

Secondary outcome measures
Treatment cost

Overall study start date
02/12/2013

Completion date
31/12/2016

Eligibility

Key inclusion criteria
Candidates for surgical treatment of Benign Prostatoc Hyperplasia (BPH):
1. Prostate volume >60ml
2. Qmax <15ml/s
3. Post-void residual (PVR) <150ml
4. Insufficient conservative or pharmacological treatment of BPH
5. Urodynamic confirmation of bladder outlet obstruction

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
90

Key exclusion criteria
1. Prostate volume <60ml
2. Qmax >15ml/s
3. Post-void residual (PVR) >150ml

Date of first enrolment
20/03/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Greece

Study participating centre
University Hospital of Patras
Rion
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26504

Sponsor information

Organisation
University Hospital of Patras

Sponsor details
Department of Urology
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Sponsor type
Other

ROR
https://ror.org/03c3d1v10

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Our intention is to publish in international journals and as abstracts in congresses the results obtained by the study.

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	results	23/02/2021	26/02/2021	Yes	No