

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

Submission date 18/05/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/02/2021	Condition category Cancer	<input type="checkbox"/> 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 erectile 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

Contact details
University of Hospital of Patras
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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 resection of 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

Patras

Greece

26504

Sponsor information

Organisation

University Hospital of Patras

Sponsor details

Department of Urology

Rion

Patras

Greece

26504

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