

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>18/05/2015   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>25/06/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>26/02/2021       | <b>Condition category</b><br>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  
Department of Urology  
Rion  
Patras  
Greece  
26504

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

Treatment cost

**Completion date**

31/12/2016

**Eligibility****Key inclusion criteria**

Candidates for surgical treatment of Benign Prostatic 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**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

**ROR**

<https://ror.org/03c3d1v10>

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded

# Results and Publications

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 23/02/2021   | 26/02/2021 | Yes            | No              |