# A Randomised Controlled Trial to Assess the Effectiveness and Cost Effectiveness of TURP, Laser and Watchful Waiting in the Treatment of Bladder Outflow Obstruction

Submission date	Recruitment status  No longer recruiting	Prospectively registered			
23/01/2004		☐ Protocol			
Registration date 23/01/2004	Overall study status Completed	Statistical analysis plan			
		[X] Results			
Last Edited	Condition category	Individual participant data			
18/01/2010	Urological and Genital Diseases				

## Plain English summary of protocol

Not provided at time of registration

## Contact information

# Type(s)

Scientific

#### Contact name

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## Additional identifiers

# Protocol serial number

941003 г245/02340

# Study information

#### Scientific Title

#### Acronym

The CLasP Study

#### **Study objectives**

Ten to fifteen percent of men aged 40 undergo transurethral prostatectomy (TURP) in their lifetime.

About 20% do not achieve satisfactory symptomatic results, 5% to 10% suffer major morbidity and 0.2% to 1% die from the procedure. The annual cost of TURP in the USA is in excess of \$3,000,000,000. New, less invasive treatments are now available including laser treatment which may be provided as a day-case procedure. It is unclear how laser treatment compares with TURP or indeed with conservative treatment (watchful waiting - reassurance and advice) in terms of cost, effectiveness, improvement in quality of life and urodynamic outcome. These deficiencies in knowledge are clearly very important to the NHS which cannot afford to take up high cost, high technology treatments unless they are shown to be of clear benefit. We propose carrying out a randomised controlled trial comparing TURP, laser treatment and watchful waiting in men who would normally undergo TURP.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Bladder outflow obstruction in men

#### **Interventions**

- 1. Laser therapy with a noncontact, side firing neodymium:YAG probe
- 2. TURP (standard transurethral prostatic resection)
- 3. Watchful waiting (conservative management, including monitoring without active intervention)

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

- 1. International Prostate Symptom Score (I-PSS)
- 2. Maximum urinary flow rate
- 3. A composite measure of success based on I-PSS and maximum urinary flow rate categories
- 4. I-PSS quality of life score
- 5. Post-void residual urine volume

## Key secondary outcome(s))

- 1. Treatment failure
- 2. Hospital stay
- 3. Major complications.

#### Completion date

30/09/1997

# **Eligibility**

#### Key inclusion criteria

Men with uncomplicated lower urinary tract symptom that is not acute or chronic urinary retention.

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Other

#### Sex

Male

#### Key exclusion criteria

Does not match inclusion criteria

#### Date of first enrolment

10/01/1994

#### Date of final enrolment

30/09/1997

# Locations

#### Countries of recruitment

United Kingdom

England

Study participating centre University of Newcastle Newcastle upon Tyne United Kingdom NE2 4HH

# Sponsor information

#### Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

# Funder(s)

## Funder type

Government

#### Funder Name

NHS Executive Northern and Yorkshire (UK)

# **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?
Results article	results for men with chronic urinary retention	01/07 /2000		Yes	No
Results article	results for men with symptoms associated with benign prostatic enlargement	01/07 /2000		Yes	No
Results article	results	01/07 /2001		Yes	No
Results article	results	01/10 /2003		Yes	No
Other publications	economic evaluation	01/12 /2002		Yes	No