

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/01/2010	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

941003 r245/02340

# 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

10/01/1994

## **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

## **Age group**

Other

## **Sex**

Male

## **Target number of participants**

106 (added 15/01/10; see publication [2])

## **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**

England

United Kingdom

**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)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

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