

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 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/01/2010	Condition category 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

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

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