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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
18/01/2010

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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