ISRCTN23921450 https://doi.org/10.1186/ISRCTN23921450

A randomised controlled trial comparing the efficacy, safety and cost-effectiveness of transurethral resection (TURP), laser vaporisation (LVAP), transurethral needle ablation (TUNA) and microwave thermoablation (MTA) of the prostate

Submission date
25/04/2003

Registration date
25/04/2003

Last Edited
14/10/2009

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
HTA 94/04/08

Study information

Scientific Title

Study objectives
50% of men over 60 years will experience symptoms attributable to benign prostatic enlargement (BNE). The traditional treatment of TURP is efficacious but carries a mortality of 0.5-1% rising to 8% in the over 80s. The overall morbidity is around 80% and has significant implications for quality of life following surgery. The proposed RCT will comprehensively compare the four surgical options TURP, LVAP TUNA and MTA in terms of efficacy, morbidity, cost and overall health gain. The evidence will be used to examine the relative efficiency of each alternative. Clinicians and purchasers of health care need the results of such analyses before deciding whether or not to invest finite resources in newer treatments.

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)
Not Specified

Health condition(s) or problem(s) studied
Benign prostatic enlargement (BNE)

Interventions
Please note that this trial was terminated due to poor recruitment.

A comparison of the 4 surgical options: TURP, LVAP, TUNA and MTA

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Efficacy, morbidity, cost and overall health gain.

Key secondary outcome(s))
Not provided at time of registration.

Completion date
31/05/1999

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Men over 60 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
Male

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/06/1996

Date of final enrolment
31/05/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Urology
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration