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	Recruitment status	Prospectively registered
25/04/2003	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/04/2003	Stopped	Results
Last Edited	Condition category	Individual participant data
14/10/2009	Urological and Genital Diseases	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