

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	Recruitment status Stopped	☐ Prospectively registered
Registration date 25/04/2003	Overall study status Stopped	☐ Protocol
Last Edited 14/10/2009	Condition category Urological and Genital Diseases	☐ 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

Contact name

Mr Chris Chapple

Contact details

Department of Urology
Central Sheffield University Hospitals NHS Trust
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF
+44 (0)114 2712559/3047
c.r.chapple@shef.ac.uk

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