

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	<input type="checkbox"/> Prospectively registered
Registration date 25/04/2003	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 14/10/2009	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Efficacy, morbidity, cost and overall health gain.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/06/1996

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

Age group

Senior

Sex

Male

Target number of participants

Not provided at time of registration.

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

England

United Kingdom

Study participating centre

Department of Urology

Sheffield

United Kingdom

S10 2JF

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

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Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration