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# Randomised evaluation of alternative electrosurgical modalities to treat bladder outflow obstruction in men with benign prostatic hyperplasia (BPH).

**Submission date**
25/04/2003

**Recruitment status**
No longer recruiting

**Registration date**
25/04/2003

**Overall study status**
Completed

**Last Edited**
08/11/2022

**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

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
HTA 94/04/09

# Study information

### Scientific Title
Randomised evaluation of alternative electrosurgical modalities to treat bladder outflow obstruction in men with benign prostatic hyperplasia (BPH).

### Study objectives
Many of the newer means of treating symptomatic BPH require expensive new equipment which requires significant additional capital investment. We consider that before investing in such equipment we should evaluate cheaper electrosurgical methods which may be similarly efficacious.

### 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)
Hospital

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Urological and genital diseases: Other urological and genital disease

### Interventions
1. Transurethral resection of the prostate (TURP)
2. Transurethral diathermy vaporisation of the prostate (TUDVP).
Perioperative complications and time to discharge, determined by strictly defined criteria will be compared.

### Intervention Type

Other

### Phase
Not Specified

### Primary outcome measure
The efficacy of the operation will be assessed by symptom scores, urine flow rate studies at two months and one year after surgery. A questionnaire covering adverse events, quality of life, impact on sexual function and customer satisfaction will be administered preoperatively and at each visit by a trained nurse counsellor. This trial will be coordinated and the results analysed for safety, effectiveness and cost benefit in collaboration with the Prostate trials Office (PROTO) at Bristol.

### Secondary outcome measures
Not provided at time of registration.

### Overall study start date
01/06/1996

### Completion date
31/07/2001

## Eligibility

### Key inclusion criteria
530 men with BPH causing bladder outflow obstruction will be recruited from four centres: one teaching hospital and three district general hospitals.

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Male

### Target number of participants
530

### Key exclusion criteria
Not provided at time of registration.

### Date of first enrolment
01/06/1996

### Date of final enrolment
31/07/2001

## Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Academic Urological Unit**
London
United Kingdom
E1 1BB

# Sponsor information

**Organisation**
Department of Health (UK)

**Sponsor details**
Quarry House
Quarry Hill
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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
Not provided at time of registration

## 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 | HTA monograph | 01/02/2005 | | Yes | No |