

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

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|----------------------------------------|--------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>25/04/2003   | <b>Recruitment status</b><br>No longer recruiting            | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>25/04/2003 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>08/11/2022       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                              | <input checked="" type="checkbox"/> Results          |
|                                        |                                                              | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

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.

## Primary study design

Interventional

## Study design

Randomised controlled trial

## Study type(s)

Not Specified

## 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(s)

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.

**Key secondary outcome(s)**

Not provided at time of registration.

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Male

**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**

United Kingdom

England

**Study participating centre**

Academic Urological Unit

London

United Kingdom

E1 1BB

# 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

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? |
|---------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | HTA monograph | 01/02/2005   |            | Yes            | No              |