

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/11/2022	<b>Condition category</b> 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

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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**

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