

Transurethral high power (80W) potassium-titanyl-phosphate (KTP) laser vapourisation of the prostate compared with holmium laser ablation of the prostate: a single-centre randomised controlled trial in patients with obst. benign prostatic hyperplasia

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/10/2014	Condition category Surgery	<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

N0355178146

Study information

Scientific Title

Study objectives

To determine which of the currently used energy delivery systems in laser prostatectomy provides for the most durable clinical outcomes.

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Surgery: Prostatectomy

Interventions

Patients will be invited to participate in the study from the out-patient clinic at the time a decision for surgical intervention has been made. They will have 2-3 weeks to consider whether or not they wish to participate and those electing to join the study will be asked to contact the Clinical Nurse Specialist for formal enrolment and randomization. All patients will be given appropriate information leaflets outlining the aims of the study. Patients electing to join the study will not undergo any further or additional investigations over and above that which is currently regarded as standard or routine practice within the department. The only variable they will submit themselves to is the formal randomization to a particular treatment arm.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Improvements in flow rates and a reduction in IPSS scores

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2005

Completion date

01/05/2007

Eligibility**Key inclusion criteria**

All patients will undergo routine assessment to include uroflowmetry, prostate size assessment, PSA testing and an IPSS score. Those between the ages of 55-75 and have Qmax flow rates of <15 ml/sec and an IPSS score of > 12 (moderate-severe LUTS) and have PSA measurements within the normal range will be eligible for the study. Patients with prostate volumes of between 40-120 cc will be deemed suitable for laser ablation surgery.

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

80

Key exclusion criteria

Patients with prostate volumes of greater than 120 cc may require open surgery and those with prostate volumes of < 40 cc may simply require bladder neck incision and are therefore exclusion criteria. Patients presenting with chronic urinary retention will be excluded from the study. These patients may have atonic bladders and voiding difficulties following the procedure may be more difficult to interpret for the purposes of the study.

Date of first enrolment

01/11/2005

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Mid Essex Hospital Services NHS Trust (BH)

Chelmsford

United Kingdom

CM1 7ET

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Sponsor details

Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

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