

A prospective, randomised, double-blinded study to compare bipolar transurethral resection of the prostate (bipolar TURP) versus monopolar transurethral resection of the prostate (monopolar TURP) in terms of safety and efficacy

Submission date 21/07/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/07/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/09/2007	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

Study information

Scientific Title

Acronym

TURP

Study objectives

Bipolar devices will minimise the disadvantages of the monopolar device such as the risk of electrolyte disturbances by using saline irrigation, bleeding and the risk of nervous stimulation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

A prospective, randomised, double-blinded study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Benign Prostatic Hyperplasia (BPH)

Interventions

Patients will be randomised into either:

Group A: who will undergo a bipolar TURP

Group B: who will undergo a monopolar TURP

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Safety bipolar TURP compared with monopolar TURP by means of transurethral resection (TUR) syndrome
2. Blood loss
3. Number and severity of adverse events

Key secondary outcome(s)

1. Efficacy of bipolar TURP compared with monopolar TURP by means of IPSS or quality of life (QoL) scores

2. International index of erectile function (IIEF) score
3. Qmax
4. Cutting rate
5. Length of catheterisation
6. Length of hospital stay
7. Length of operation
8. Impact on prostate specific antigen (PSA) level
9. Number of strictures

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Candidates for transurethral resection of the prostate (TURP)
2. Qmax less than 16 ml/sec
3. International Prostate Symptom Score (IPSS) score greater than 14
4. Voided volume greater than 125
5. Patients in retention with an indwelling catheter or intermittent catheterisation
6. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. If patient is suspected to be suffering from prostate cancer
2. Prior prostate surgery, including minimal invasive therapies
3. Active urinary tract infection
4. Known or suspected neurogenic decompensated bladder (postvoid residual urine volume [PVR] greater than 400ml/sec) or compensated detrusor function
5. Immunosuppression; using prednisone
6. Known or suspected malignant disease affecting the bladder or lower urinary tract
7. 5-alpha-reductase inhibitor within the last three months before baseline
8. Alpha-blockers within the last six weeks before baseline
9. Specific severe heart disease in whom anti-coagulant therapy might jeopardize treatment outcome

Date of first enrolment

01/07/2006

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Center (AMC), Department of Urology (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Industry

Funder Name

Karl Storz (UK)

Funder Name

Academic Medical Center (AMC) (The Netherlands) - Department of Urology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes