# 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	Recruitment status	<ul><li>Prospectively registered</li></ul>
21/07/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/07/2006	Completed	Results
Last Edited	Condition category	Individual participant data
19/09/2007	Urological and Genital Diseases	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Study website

http://www.turp.nl

# Contact information

# Type(s)

Scientific

#### Contact name

Dr S.A. Lagerveld-Zaaijer

## Contact details

Academic Medical Center (AMC)
Department of Urology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5666030
S.A.Zaaijer@amc.uva.nl

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# 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

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

Treatment

# Participant information sheet

# 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 measure

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

## Secondary outcome measures

- 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 catherisation
- 6. Length of hospital stay
- 7. Length of operation
- 8. Impact on prostate specific antigen (PSA) level
- 9. Number of strictures

## Overall study start date

01/07/2006

## Completion date

31/12/2010

# Eligibility

#### Key inclusion criteria

- 1. Candidates for transurethral resection of the prostate (TURP)
- 2. Omax 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

## Age group

Adult

#### Sex

Both

## Target number of participants

94

## 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)

## Sponsor details

P.O. Box 22660 Amsterdam Netherlands 1100 DD

## Sponsor type

University/education

## **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**

# 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