A prospective, randomized, double-blinded study to compare bipolar Trans Urethral Resection of the Prostate (bipolar TURP) versus monopolar Trans Urethral Resection of the Prostate (monopolar TURP) in terms of safety and efficacy.

Gepubliceerd: 13-06-2006 Laatst bijgewerkt: 13-12-2022

Bipolar devices will minimize the disadvantages of the monopolar device; risk of electrolyte disturbances by using saline irrigation, bleeding and the risk of nervous stimulation

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19882

Bron
Nationaal Trial Register

Verkorte titel
Monopolar-bipolar TURP

Aandoening

Benign Prostate Obstruction/Hyperplasia who are eligible for an TURP

Ondersteuning

Primaire sponsor: Academic Medical Center, Department of Urology
Overige ondersteuning: Academic Medical Center, Department of Urology
Technical Support: Karl Storz

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Safety bipolar TURP compared with monoploar TURP by means of TUR syndrome, blood loss, number and severity of adverse events.

Toelichting onderzoek

Achtergrond van het onderzoek

Patients who are eligible for an operative treatment with benign prostate obstruction will be randomized in either the bipolar TURP or in the monopolar TURP. The two arms will be compared in terms of safety and efficacy with a follow up of 36 months.

Doel van het onderzoek

Bipolar devices will minimize the disadvantages of the monopolar device; risk of electrolyte disturbances by using saline irrigation, bleeding and the risk of nervous stimulation

Onderzoeksproduct en/of interventie

Patients will be randomized in either:
Group A: Who will undergo a bipolar TURP or in
Group B: who will undergo a monopolar TURP.

Contactpersonen

Publiek

Academic medical Center (AMC) Department of Urology
P.O. Box 22660
S.A. Zaaijer
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5666030

Wetenschappelijk

Academic medical Center (AMC) Department of Urology
P.O. Box 22660
S.A. Zaaijer
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5666030

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Candidates foor TURP;
2. Qmax < 16 ml/sec;
3. IPSS score >14;
4. Voided volume > 125;
5. Patients in retention with an indwelling catheter or intermittent catheterisation;
6. Given informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Suspected from prostate cancer;
2. Prior prostate surgery, including minimal invasive therapies;
3. Active urinary tract infection;
4. Known or suspected neurogenic decompensated bladder (PVR>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 3 months before baseline;
8. Alpha-blockers within the last 6 weeks before baseline;
9. Specific severe heart disease in whom anti-coagulant therapy might jeopardize treatment outcome.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	94
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-06-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL643
NTR-old	NTR703

Register	ID
Ander register	: N/A
ISRCTN	ISRCTN16583435

Resultaten

Samenvatting resultaten
N/A