Effect van Mirabegron op de urethrale druk tijdens urodynamisch onderzoek

Gepubliceerd: 03-11-2014 Laatst bijgewerkt: 18-08-2022

Effect of beta 3 receptor agonist on urethral pressure variations during urodynamic investigation

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

Samenvatting

ID

NL-OMON26653

Bron
NTR

Aandoening

urinary urgency, urinarinary incontinence, over active bladder symptoms

Ondersteuning

Primaire sponsor: P. Groenendijk, Medisch Centrum Haaglanden, den haag
Overige ondersteuning: Unrestricted educational grand Astellas pharma BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Effect of mirabegron on urethral pressure variations

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Patients with overactive bladder symptoms have an increased voiding frequency and a sudden need to urinate (‘urinary urgency’). In a large proportion of these patients detrusor (=bladder muscle) overactivity can be demonstrated during the filling (urine-storage) phase of a urodynamic investigation (= investigation to measure bladder function or dysfunction, which explains the pathophysiology of the symptoms). With or without urodynamic diagnosis, the mainstay of treatment for patients with overactive bladder symptoms is oral anticholinergical or antimuscarinergical pharmacotherapy (‘bladder muscle relaxants’).

During the filling (urine storage) phase of a urodynamic investigation however, urethral (bladder outlet) pressure variations can be observed in association with detrusor overactivity in a proportion of patients. The clinical relevance and or the role of urethral pressure variations in the pathophysiology are yet not precisely established.
Recently a beta 3 adrenoreceptor agonist is approved for the treatment of overactive bladder symptoms. The beta 3 adrenoreceptor agonist stimulates inhibition of detrusor overactivity (and is clinically and urodynamically effective in this regard). Theoretically beta 3 adrenoreceptor agonists may, apart from inhibition of detrusor overactivity, stimulate the urethra to maintain closure –contraction.

Patients with urethral pressure variations might therefore especially benefit from beta 3 adrenoreceptor agonist since theoretically the treatment might ‘stabilize’ the urethral pressure and therefore reduce symptoms of ‘urinary urgency’. The effect of a beta 3 adrenoreceptor agonist on the urethral pressure and or on urethral pressure variations during filling cystometry is however unknown.

Objective: To evaluate the effect of beta 3 adrenoreceptor agonist on urethral pressure variations during filling phase and to initially explore the possibilities for individualisation of treatment for overactive bladder symptoms.

Study design: Multicentre prospective open label observational cohort study to evaluate the short term urodynamic effect of treatment with a beta 3 adrenoreceptor agonist, in patients with symptoms of overactive bladder.

Study population: Adult female patients with overactive bladder symptoms.

Intervention (if applicable): After initial urodynamic investigation a cohort of patients will be treated for 6 weeks with beta 3 adrenoreceptor agonist to conclude with – endpoint - urodynamic investigation while on medication. The study is an observational cohort with invasive – endpoint- measurement.
Main study parameters/endpoints: Primary endpoint is the difference in urethral pressure variations before and on (6 weeks) treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Treatment with beta 3 adrenoreceptor agonist is clinically safe and effective. Urodynamic testing at the start of treatment is standard in patients resistant to first line treatment. However, also in second line treatment a pragmatic approach on the basis of symptoms without further urodynamic tests is usually the first step of management in many practices. The second urodynamic investigation, and for some patients also the initial urodynamic investigation will be extra, as a consequence of our research question.

Doel van het onderzoek

Effect of beta 3 receptor agonist on urethral pressure variations during urodynamic investigation

Onderzoeksopzet

Start is date of first urodynamic investigation.

Second time point is second urodynamic investigation, 6 weeks after start of Mirabegron

Onderzoeksproduct en/of interventie

Start of mirabegron

Second urodynamic investigation

Voluntary questionnaire about sexual function

Contactpersonen

Publiek

Urologist MCH
P. Groenendijk
Lijnbaan 12
Den Haag 2512 VA
The Netherlands
070-3303055

Wetenschappelijk

Urologist MCH
P. Groenendijk
Lijnbaan 12

Den Haag 2512 VA
The Netherlands
070-3303055

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Female patients, above age of 18, mentally fit to consent and indication for treatment with Mirabegron. Bothersome OAB symptoms. Voiding diary volume urine less then 2200ml.

• Signed informed consent

• May have had –unsatisfying- treatment with antimuscarinergic medication

• Willing to stop medication for lower urinary tract dysfunction 2 days before urodynamic investigation (at entry of study)

• Willing to start B3AA (mirabegron)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Contraindications for the use of Mirabegron (severely impaired kidney- or liver function)

• Sediment + or clinical signs of UTI at the start of the urodynamic investigation

• Necessity to perform CIC or significant post void residual (>100mL).

• Significant voiding abnormalities; bladder outlet obstruction (UDI >grade 1 or BOOI >20) or underactive or acontractile detrusor.

• Unwilling or unable – according to treating physician- to stop current treatment for lower urinary tract dysfunction.

• Treatment with intradetrusor botulinum toxin less than one year before urodynamic investigation (whether or not symptomatically effective)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2014
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-11-2014
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	NL4760
NTR-old	NTR4888
CCMO	NL nummer

Resultaten