Effect van Mirabegron op de urethrale druk tijdens urodynamisch onderzoek

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26653

Source
NTR

Health condition

urinary urgency, urinarinary incontinence, over active bladder symptoms

Sponsors and support

Primary sponsor: P. Groenendijk, Medisch Centrum Haaglanden, den haag
Source(s) of monetary or material Support: Unrestricted educational grand Astellas pharma BV

Intervention

Outcome measures

Primary outcome

Effect of mirabegron on urethral pressure variations

Secondary outcome

• Difference of total number of urethral pressure variations on urodynamic investigation after treatment, compared to initial urodynamic investigation.

• Difference in volume to first detrusor contraction between ‘before’ and ‘on treatment’.

• Differences in volume to first sensation of filling, normal desire to void and strong desire to void, between ‘before’ and ‘on treatment’.

• Difference in volume to first urethral pressure drop between ‘before’ and ‘on treatment’.

• Difference in largest pressure drop (cmH2O) between ‘before’ and ‘on treatment’.

• To explore the association of symptoms and voiding diary data before and on treatment with a beta 3 adrenoreceptor agonist with significant urethral pressure variations/ urethral pressure drops during urodynamic investigation (before and on treatment).

• Sexual function as measured with a questionnaire before and on treatment with beta 3 adrenoreceptor agonist.

Comparison of (grouped average) individual before and on treatment effect(s) of a beta 3 adrenoreceptor agonist on symptoms and voiding diary and urodynamic parameters

Study description

Background summary

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.

Study objective

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

Study design

Start is date of first urodynamic investigation.

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

Intervention

Start of mirabegron

Second urodynamic investigation

Voluntary questionnaire about sexual function

Contacts

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

• 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)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2014
Enrollment:	75
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-11-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4760
NTR-old	NTR4888
CCMO	NL nummer

Study results