Does the alpha blocker Silodosin improve the bladder emptying in patients with MS?

No registrations found.

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

Summary

ID

NL-OMON26059

Source
NTR

Brief title
Alpha blockers and MS

Health condition

Multiple Sclerosis
MS
neurogene blaas
neurogenic bladder
residual urine
urine residu
bladder residual volume
blaasresidu
alpha blockers
alpha blokkers

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Stichting Coolsingel

Intervention

Outcome measures

Primary outcome

- Residual urine

Secondary outcome

- Quality of life (questionnaire: SF-Qualiveen)

- Symptom scores of voiding complaints (questionnaires: UDI-6 and IIQ-7)

Study description

Background summary

This study is a prospective, placebo-controlled, double-blind, randomized study.

The objective of the study is to investigate if the alpha blocker Silodosin improves the bladder emptying and the quality of life in patients with MS.

30 female patients (18 years or older) with relapsing-remitting MS and bladder emptying dysfunction will be recruited and divided into 2 groups of 15 patients. One group receives Silodosine for 6 weeks and one group receives placebo. Residual urine and quality of life and symptom score questionnaires will be measured at t = 0 en t = 6 weeks.

Study objective

The hypothesis is that the "uro-selective" alpha blocker Silodosin improves bladder emptying in women with MS

Study design

At t=0 and t=6 weeks.

Intervention

The investigational product is Silodosin, a "uro-selective" alpha blockers. The dosage is 8 mg once daily per os. One group receives Silodosin for 6 weeks while the second group is treated with a placebo during the same period.

Contacts

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Eligibility criteria

Inclusion criteria

- Female

- Age 18 years or older

- Relapsing-remitting MS

- Residual urine 80 ml ¡§C 250 ml

- Adequate understanding of the Dutch language

Exclusion criteria

- Dependency of wheel chair

- Being bedridden

- Indwelling catheter

- Clean intermittent catheterization

- Acute attack of MS

- Current treatment with an alpha-blocker

- Pregnancy/breastfeeding

- Severe kidney dysfunction

- Orthostatic hypotension

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-02-2016
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47090
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5545
NTR-old	NTR5666
CCMO	NL54539.078.15
OMON	NL-OMON47090

Study results

Summary results
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