Are alpha blockers effective in the treatment of bladder elimination problems in female patients with Multiple Sclerosis?

Published: 21-01-2016
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Improves the alpha blocker Silodosin the bladder emptying in patients with MS? Improves the alpha blocker Silodosin the quality of life of patients with MS?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON47090

Source
ToetsingOnline

Brief title
Alpha blockers and Multiple Sclerosis (MS)

Condition

- Demyelinating disorders
- Bladder and bladder neck disorders (excl calculi)

Synonym
Bladder dysfunction in MS, bladder dysfunction in Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Stichting Coolsingel

Intervention

Keyword: Alpha blockers, Bladder elimination problems, Multiple Sclerosis (MS), Quality of life

Outcome measures

Primary outcome

Residual urine, measured within 10 minutes after a voluntary void at t=0 and

t=6 weeks.

Secondary outcome

- Quality of life (questionnaire: Qualiveen) at t=0 and t=6 weeks.

- Symptom scores of voiding complaints (questionnaires: UDI-6 and IIQ-7) at t=0

and t=6 weeks.

Study description

Background summary

On theoretical grounds, on the basis of clinical and pre-clinical studies, and on personal experience it can be expected that "uro-selective" alpha blockers greatly improve bladder emptying in MS patients. This results in a decrease of the need for CISC/indwelling catheter with a consecutive decrease of UTI's and incontinence episodes. The overall outcome is an improvement of the quality of life of patients with MS.

Study objective

Improves the alpha blocker Silodosin the bladder emptying in patients with MS?
Improves the alpha blocker Silodosin the quality of life of patients with MS?

Study design

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

Intervention

One group receives the alpha blocker Silodosin during 6 weeks while the second group is treated with placebo during the same period.

Study burden and risks

The burden and risks associated with the participation are minimal. The subjects are asked to complete three short questionnaires two times during a 6 week period and two times residual urine measurements will be done. After 3 weeks an evaluation of side-effects will be performed by telephone. Furthermore, the number of study visits is two, this is no extra visit compared to standard treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Female
- Age >= 18 years
- Any form of MS
- Residual urine 60 ml - 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 phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-02-2016
Enrollment:	30

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Silodyx
Generic name:	Silodosin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-01-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-02-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-02-2018

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26059
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2015-002820-20-NL
CCMO	NL54539.078.15
OMON	NL-OMON26059