The effect of botulinum toxin type A injections in the m. rectus femoris in stroke patients presenting with stiff knee gait

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To determine the effect of botulinum toxin type A injections in stroke patients with stiff knee gait.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON39359

Source
ToetsingOnline

Brief title
Botulinum toxin type A injections in stiff knee gait

Condition

- Central nervous system vascular disorders
- Vascular hypertensive disorders

Synonym
stiff knee gait, stiff-legged knee

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh

Source(s) of monetary or material Support: Roessingh research and development /Innovatie Centrum gelden

Intervention

Keyword: botulinum toxin type A, rectus femoris, stiff knee gait, stroke

Outcome measures

Primary outcome

- VICON 3D analysis to determine knee flexion during swing phase

- Pulmonary function test to determine the energy cost during walking (measured with CosMed K4b2)

- Electromyogram (EMG) measurements

- BORG and VAS questionnaire for tonus

- Duncan-Ely test

- Kinematics (measured with VICON 3D gait analysis)

- Kinetics (measured with force plates)

- Muscle Activation in Pendulum, Passive and Active Movements Test (MAPPAM)

- Motricity Index

- Rivermead Mobility Index

- 6 minutes walk test

- Timed Up and Go test

Secondary outcome

- Stroke Impact Scale

Study description

Background summary

In the Netherlands live about 18.000 Cerebro Vascular Accident (CVA)-patients which discover problems with walking caused by insufficient footclearance. Causes of problems with the footclearance during the swing phase of gait are a combination of diminished dorsal flexion of the ankle, knee flexion and hip flexion. A diminished knee flexion during swing is defined a stiff knee gait. A stiff knee gait is often caused by an overactivity of the m. rectus femoris. A stiff knee caused by an overactivity of the rectus femoris can improve by botulinum toxin type A injections. Botulinum toxin type A injections create a local muscle paralysis, which decrease overactivity in the m. rectus femoris.

Study objective

To determine the effect of botulinum toxin type A injections in stroke patients with stiff knee gait.

Study design

A randomized controlled cross-over design. Patients will be randomized in group A or group B. Randomisation will be done by an independent person and takes place by blockrandomisation. A computer generated model randomize blocks of four patients, two patients in group A and two patients in group B. Interventions will be allocate after inclusion. Subjects and researchers who measure outcomes are blinded. Group A receives first a placebo-injection and group B receives first a botulinum toxin type A injection. After 5 months (4 months effect of the intervention + 1 month wash-out) group A receives a botulinum toxin type A injection and group B receives a placebo-injection.

Intervention

Botulinum toxin type A injections (Botox®). Botox® is a neurotransmitter which reduce the release of acetylcholine. This causes a muscle paralysis for 12 weeks. Botulinum toxin type A is injected at 6 points in the m. rectus femoris (200U).
NatriumChloride (NaCl) is the placebo injection and is injected at the same way as the botulinum toxin type A injection.

Study burden and risks

In a period of 7 months patient comes 4 mornings at the Roessingh Research and Development for measurements. Patient walks 8 times over a distance of 7,5 metre with 3 different velocities, do simple tests and fill in 3 questionnaires. There is a very small risk that the patients report very little adverse effects of the injections. In case of presence of adverse effects they will disappear in a little time. There are no known definitive adverse effects of botulinum toxin type A injections.

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

age over 18 years
6 months post stroke
patient walks with a stiff knee gait caused by an overactivity of the m. rectus femoris
able to walk independent
overactivity of the m. rectus femoris, established with EMG-measures

Exclusion criteria

presence of other constraints in joints who impede walking
neurological problems not causes by a Cerebro Vascular Accident
patient walks with a diminished knee flexion as a result of an orthopedic cause

myasthenia gravis or Eaton-Lambert syndrome
progressive clinical picture which influence the gait pattern
use of amfotericine B en/of amsacrine
pregnancy / nursing mothers

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2011
Enrollment:	26
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NatriumChlorid
Generic name:	NaCl 0,9%
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	onabotulinumtoxinA
Generic name:	BOTOX
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	13-04-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-04-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	12-03-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
EudraCT	EUCTR2009-018226-29-NL
CCMO	NL31114.044.10
Other	TC = 2169