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

Published: 13-04-2010
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To determine the effect of botulinum toxin type A injections in stroke patients with stiff knee gait.

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|---|---|
| **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

**Public**
Revalidatiecentrum Het Roessingh

Roessinghsbleekweg 33
enschede 7522 AH
NL
**Scientific**
Revalidatiecentrum Het Roessingh

Roessinghsbleekweg 33
enschede 7522 AH
NL

# 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

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| 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

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| 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 |