Botulinum toxin type A injections in stiff knee gait.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29171

Source
NTR

Health condition

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.

Keywords: stroke, stiff knee gait

Sponsors and support

Primary sponsor: Roessingh Research and Development
Roessinghsbleekweg 33
7577 AH Enschede
Source(s) of monetary or material Support: Roessingh Research and Development, Roessingh Rehabilitation Centre

Intervention

Outcome measures

Primary outcome

1. VICON 3D analysis to determine knee flexion during swing phase;

2. Electromyogram (EMG) measurements;

3. BORG and VAS questionnaire for tonus;

4. Duncan-Ely test;

5. Kinematics (measured with VICON 3D gait analysis);

6. Kinetics (measured with force plates);

7. Muscle Activation in Pendulum, Passive and Active Movements Test (MAPPAM);

8. Motricity Index;

9. Rivermead Mobility Index;

10. 6 minutes walk test;

11. Timed Up and Go test.

Secondary outcome

Stroke Impact Scale.

Study description

Background summary

Background of the study:

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.

Objective of the study:

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.

Study population:

26 stroke patients presenting with a stiff knee gait.

Inclusion criteria:

1. Age over 18 years;

2. 6 months post stroke;

3. Patient walks with a stiff knee gait, caused by an overactivity of the m. rectus femoris;

4. Able to walk independent.

Exclusion criteria:

1. Presence of other constraints in joints who impede walking;

2. Neurological problems not causes by a Cerebro Vascular Accident;

3. Patient walks with a diminished knee flexion as a result of an orthopedic cause;

4. Progressive clinical picture which influence the gait pattern.

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.

Primary study parameters/outcome of the study:

1. VICON 3D analysis to determine knee flexion during swing phase;

2. Electromyogram (EMG) measurements;

3. BORG and VAS questionnaire for tonus;

4. Duncan-Ely test;

5. Kinematics (measured with VICON 3D gait analysis);

6. Kinetics (measured with force plates);

7. Muscle Activation in Pendulum, Passive and Active Movements Test (MAPPAM);

8. Motricity Index;

9. Rivermead Mobility Index;

10. 6 minutes walk test;

11. Timed Up and Go test.

Secundary study parameters/outcome of the study:

Stroke Impact Scale (SIS)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Study objective

N/A

Study design

t0: baseline measurement before intervention;

t1: effect measurement (6 weeks after injection);

t2: baseline measurement after cross-over (5 months after t0);

t3: effect measurement (6 weeks after t2 measurement).

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.

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Eligibility criteria

Inclusion criteria

1. Age over 18 years;

2. 6 months post stroke;

3. Patient walks with a stiff knee gait, caused by an overactivity of the m. rectus femoris;

4. Able to walk independent.

Exclusion criteria

1. Presence of other constraints in joints who impede walking;

2. Neurological problems not causes by a Cerebro Vascular Accident;

3. Patient walks with a diminished knee flexion as a result of an orthopedic cause;

4. Progressive clinical picture which influence the gait pattern.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2013
Enrollment:	26
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL2052
NTR-old	NTR2169
Other	EudraCT : 2009-018226-29
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A