The effect of Botulinum toxin treatment on the activity level of patients with a spastic hemiparesis after stroke

Published: 12-10-2006
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To investigate the effect of Botulinum toxin treatment on the activity level of people with spastic hemiparese after stroke.

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational non invasive

Summary

ID

NL-OMON29937

Source
ToetsingOnline

Brief title
activity level of stroke patients after Botulinum toxine treatment

Condition

- Congenital and peripartum neurological conditions

Synonym
cerebro vascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Allergan,bedrijf

Intervention

Keyword: activity level, activity monitoring, Botulinum toxin, stroke

Outcome measures

Primary outcome

Activity level (measured by the ADL-monitor)

Secondary outcome

- activity level (measured by the SF-36)

- walking ability (measured using instrumented gaitanalysis)

Study description

Background summary

Decreased walking ability is one of the major disabilities after stroke. In patients with spastic hemiparesis main reasons for this disability are increased tonus and spasms in the hemiplegic limb. In order to decrease the tonus and spasms and to improve walking ability, the muscles could be localy treated by injections of botulinum toxin. The effect of this treatment at the level of the muscle and on the gaitpattern has been investigated previously. However, untill now, the effect of the injections on activity level is unknown.

Study objective

To investigate the effect of Botulinum toxin treatment on the activity level of people with spastic hemiparese after stroke.

Study design

Prospective cohort study

Study burden and risks

Botulinum toxin injections and physical examination are part of the regular treatment.
Gait analysis before and 9 weeks after intervention is part of the regular intervention. Gait analysis 6 months after intervention is a regular part of

the intervention of childeren having botulinum toxin injections but not of the intervention of adults after stroke. Because people only have to walk a maximum of 10 metres about 10 times, this will not be an intense burden. Walking ability is also registrated during gait analysis.
Questionning the SF-36 is not part of the regular intervention but is expected not to be an intense burden.
To monitor the activities in daily living is not part of the regular intervention. Because the activities are monitored using a portable datalogger (dimension: 10*13*3.5 cm; weight: 650 gram) that is worn in a belt around the patients waist and a sensor that is put on the thigh for a period of 36 hours, this will possibly be a burden for the patients.
None of the interventions or measurements will bring any extraordinary risks.

Contacts

Public
Vrije Universiteit

van der Boechorststraat 9
1081 BT Amsterdam
Nederland
Scientific
Vrije Universiteit

van der Boechorststraat 9
1081 BT Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age 18 - 65 years
- at least 6 months post-injury
- indication for injections of Botulinum toxin because of spastic gait

Exclusion criteria

- simultaneously undergoing other treatments related to gait training
- wheelchair dependent
- having contractures on the lower limbs
- serious cognitive impairments (not able to learn and/or train anything)
- serious comorbidities related to mobility
- having had injections of botulinum toxin less than 6 months ago

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL13524.029.06