Added-value of early post-stroke spasticity reduction during arm-hand rehabilitation treatment on improving functional arm-hand skill performance in sub acute stroke patients with a severely or moderately affected arm-hand

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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-OMON43425

Source
ToetsingOnline

Brief title
Added-value of early post-stroke spasticity reduction

Condition

- Central nervous system vascular disorders

Synonym
subacute stroke spasticity

Research involving

Human

Sponsors and support

Primary sponsor: Adelante
Source(s) of monetary or material Support: Ipsen Farmaceutica BV,This study is sponsored by a grant from Ipsen Farmaceutica BV.

Intervention

Keyword: arm-hand function, arm-hand skill performance, early spasticity reduction, subacute stroke

Outcome measures

Primary outcome

- Action Research Arm Test (ARAT), gauging functional capacity.

Secondary outcome

- Fugl-Meyer Motor Assessment (FM), gauging arm-hand function level;

- JAMAR strength test, gauging muscle strength;

- Motricity Index (MI): Functional strength measurement during performance of

daily tasks;

- Modified Ashworth Scale (MAS): gauging spasticity levels in the upper

extremity;

- ABILHAND, gauging perceived level of arm-hand skill/activity proficiency;

- Bilateral arm activity monitoring: As to actual arm-hand skill performance,

bilateral activity monitors (3D accelerometry, AX3, Axivity Ltd) will be worn

around both wrists.

Study description

Background summary

Whereas there is a myriad of literature on the benefits of reducing spasticity on rehabilitation training effects regarding arm-hand function (AHF) and arm-hand skill performance (AHSP) in chronic stroke patients using Botulinumtoxin-A, a review of scientific literature revealed that thus far little evidence is available on the added-value of early spasticity reduction during rehabilitation training on the improvement of AHF and AHSP in sub-acute stroke patients. Clinical experience showed that already in an early, sub-acute phase post-stroke, in a number of patients with a moderate to severely affected arm and hand (Utrecht Arm-hand Test (UAT) score 1-3), moderate to severe grades of spasticity (Modified Ashworth Scale (MAS) scores 1+ to 3) occur that seriously hinder AHF and AHSP treatment, leading to a slowing down of functional recovery of the patient. The present study will investigate the added-value of reduction of early signs of spasticity in the sub-acute phase after stroke on arm-hand rehabilitation treatment outcome involving a well-described rehabilitation intervention (*treatment-as-usual*), i.e. CARAS.

Study objective

The aim of the present study is to investigate the added-value of reduction of early signs of spasticity in the upper extremity on improving functional arm-hand skill performance in sub-acute stroke patients with either a severely or moderately affected arm-hand (Utrechtse Arm-hand Test (UAT) score 1-3) and moderate to severe grades of spasticity. Therapy-as-usual (TAU), involving a regular, well-documented, concise arm-hand rehabilitation treatment (called CARAS) will be provided during each patient*s rehabilitation program. TAU will include spasticity-reducing treatment using Botulimumtoxin-A (BoNt-A) injections (as a non-investigational product) in the spastic muscles of the arm-hand.

Study design

The current study features three methodological approaches, i.e.:
i) a (multiple baseline) single case experimental design involving 10 individuals;
ii) a meta-analysis of the data of all single cases (= single arm group design);
iii) a case-matched control design in which each patient receiving early post-stroke spasticity reduction treatment (next to CARAS) will be matched (according to arm-hand capacity (ARAT) at baseline, age, gender, UAT score at baseline and level of spasticity within 5 weeks after the start of CARAS (MAS score)) to a case from a previous study called AMUSE (CCMO code: NL35681.068.11) (= non-randomised double arm group design).

Intervention

During the so-called 'therapy-as-usual' (TAU), comprising of a well-described arm-hand excercise / rehabilitation program (called CARAS), spasticity in the

arm muscles on the affected side will be reduced usingt Botulimumtoxin-A (BoNt-A) injections.

Study burden and risks

The patient may benefit from this study in that oncoming spasticity in his arm-hand may be reduced at an early stage, thus enabling him to train his arm and hand in a more functional way, thereby increasing the chance of reaching a higher level of functional outcome, enabling him to perform his daily activities better. As BoNt-A is already used extensively in clinical practice, this project poses no additional risks. The decision to use BoNt-A is entirely based on clinical necessity, i.e. when a patients is developing spasticity in the upper limb on the affected side, as established by the rehabilitation physician. Also, all measures used in the present study pose no harm to the participant. They are also used as regular clinimetrics in rehabilitation.

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 ><=18 years;
- supratentorial stroke, i.e. arteria cerebri media infarction;
- sub acute phase after stroke, i.e. between 2 weeks and 3 months post-stroke;
- severe paretic arm and hand: UAT score 1-3;
- eligible to participate in a specific arm-hand rehabilitation program (CARAS) for a period of 12 weeks;
- sufficient cognitive level, i.e. being able to understand the questionnaires and measurement instructions;
- functional disabling spasticity in the upper extremity: Modified Ashworth Scale (MAS) score 1+ to 3 (developing within 5 weeks after the start of CARAS).;As to functional disabling spasticity in the upper extremity, patients developing spasticity in the early subacute phase after stroke (i.e. within 5 weeks after the start of CARAS) with a Modified Ashworth Scale (MAS) score of 1+ to 3 will continue to participate in the study. In contrast, in patients who have a severe paretic arm and hand (UAT score 1-3) at admission to the rehabilitation centre, but who do not develop early signs of spasticity within 5 weeks after start of arm-hand treatment (thereby not being in the target group), measurements will cease.

Exclusion criteria

- severe non-stroke related co-morbidity that may interfere with arm-hand function;
- additional orthopaedic, neurological or rheumatologic impairments of the arms and/or hands and or trunk that may interfere with the execution of the measurements;
- no informed consent.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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: 28462
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56494.015.16
OMON	NL-OMON28462