Added-value of early post-stroke spasticity reduction.

Gepubliceerd: 04-08-2016 Laatst bijgewerkt: 15-05-2024

It is hypothesised that early post-stroke reduction of spasticity in the shoulder, arm and hand muscles, adjuvant to a high intensity, task-oriented arm-hand training program, improves functional arm-hand skill performance in sub-acute post-stroke...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28462

Bron
NTR

Aandoening

sub-acute stroke, arm-hand function, arm-hand skill performance, spasticity,

CVA, subacuut, arm-hand functie, arm- hand vaardigheid, spasticiteit.

Ondersteuning

Primaire sponsor: - Adelante Centre of Expertise in Rehabilitation and Audiology, Adelante

Overige ondersteuning: - Ipsen Farmaceutica BV, Hoofddorp, The Netherlands

- Adelante Centre of Expertise in Rehabilitation and Audiology, Adelante

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Action Research Arm Test (ARAT)

Toelichting onderzoek

Achtergrond van het onderzoek

- Objective:

To 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’).

Study design:

This study features 3 study designs:

i) a (multiple baseline) single case experimental design;

ii) a meta-analysis of the data of all single cases (= single arm group design);

iii) a case-matched control design matching the single cases to cases from a previous cohort study (AMUSE study) (= non-randomised double arm group design).

- Study population:

Adult sub-acute stroke patients with either a severely or moderately affected arm-hand (Utrecht Arm-hand Test (UAT) score 1-3) and moderate to severe grades of spasticity.

- Intervention (if applicable):

Reduction of early signs of spasticity in the arm-hand by using Botulinumtoxin-A (BoNt-A) during arm-hand rehabilitation treatment-as-usual as described by Franck et al. (2015) (=CARAS treatment protocol).

- Main study parameters/endpoints:

Improvement of arm-hand skill performance will be gauged by using a) the Action Research Arm Test (ARAT), gauging functional capacity; b) the ABILHAND, gauging perceived level of arm-hand skill/activity proficiency; and c) Bilateral arm accelerometry, gauging actual arm-hand skill performance in daily life. Furthermore, arm-hand function will be measured using a) Fugl-Meyer Motor Assessment (FM); b) JAMAR (grip strength); c) Motricity Index (functional strength); and d) MAS (spasticity levels in the upper extremity).

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

relatedness:

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. This increases the chance of reaching a higher level of functional outcome, which enables 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 patient 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.

Doel van het onderzoek

It is hypothesised that early post-stroke reduction of spasticity in the shoulder, arm and hand muscles, adjuvant to a high intensity, task-oriented arm-hand training program, improves functional arm-hand skill performance in sub-acute post-stroke patients with a moderately to severely affected arm-hand (UAT score 1-3) and moderate to severe grades of spasticity.

Onderzoeksopzet

1-week intervals during the 2 x 6 weeks (total 12 weeks) CARAS treatment and at 2-weeks intervals during the ensuing three months follow up

Onderzoeksproduct en/of interventie

CARAS:

Arm-hand rehabilitation treatment will be provided according to the CARAS approach as described by Franck et al. (2015). In Adelante rehabilitation centre and multiple other rehabilitation centres in the Netherlands, CARAS is ‘therapy-as-usual’ (TAU). After a standard initial clinical assessment, patients will receive arm-hand rehabilitation treatment for 2x 6 weeks. Based on the UAT scores, patients are allocated to one of three training programs, i.e.:

• CARAS program 1; severely impaired AHF subgroup (UAT=0-1),

• CARAS program 2; moderately impaired AHF subgroup (UAT=2-3) and

• CARAS program 3; mildly impaired AHF subgroup (UAT=4-7).

Program 1 is titled ‘taking care and prevention’. It is designed for stroke survivors who, due to the severity of the stroke, are not able to use their affected arm and hand for skill performance in daily life situations (non-functional arm-hand). Program 2 and 3 are high intensity, task-oriented arm-hand performance training programs in which patients learn to integrate their affected arm and hand in daily occupations to optimize their overall functional

abilities in daily situations. In this part a distinction is made between persons who have a moderately affected arm and hand, i.e. those who are able to use their affected arm and hand for passive and active stabilisation tasks, like fixating bread while making a sandwich; and persons with a mildly affected arm and hand, who are able to use their affected arm and hand instantaneously in daily situations.

CARAS is the standard therapy (therapy-as-usual) provided by physiotherapists and occupational therapists to all stroke patients with arm-hand problems who are admitted to Adelante rehabilitation centre for treatment. This means that the decision to apply CARAS is taken before inclusion of the patient in the study.

The present study focusses on patients with an initial UAT score of 1-3.

CARAS + spasticity-reducing treatment:
In order to reduce spasticity, Botulinumtoxin A (BoNt-A) will be administered once, i.e. directly following the sequence of baseline measurements in each patient who is developing (early signs of) spasticity in the upper extremity. BoNt-A will be administered by a senior rehabilitation physician at Adelante rehabilitation centre. Patients will receive BoNt-A injected according to clinical judgement into the dominant spastic muscles of the arm and/or forearm. The total maximum dose for the upper limb will be 1000U. BoNt-A dosage for individual muscles will be in line with the dose ranges reported by Dashtipour et al. (2014), het Farmacotherapeutisch Kompas, en Gracies et al. (2015). Muscles will be identified using electro stimulation or echography according to the normal practice of the clinician.

The decision to use BoNt-A is entirely based on clinical necessity, i.e. when a patient is developing spasticity in the upper limb muscles on the affected side (MAS score 1+ to 3), as established by the rehabilitation physician. After the first finding of this MAS score, the decision to apply Botulinetoxine-A will be done by the rehabilitation physician and the application itself will be done within 1 week.

Patients in the target group, i.e. those who have a severe paretic arm and hand (UAT score 1-3) at admission to the rehabilitation centre, will be asked to participate as soon as possible after admission to the rehabilitation centre. After giving informed consent, measurements will start according to the protocol described. Patients who develop early signs of spasticity in the arm and/or hand, i.e. within 5 weeks after start of arm-hand treatment (CARAS), will remain in the study. 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 to be used in the study will cease. The latter will have no consequences for the rehabilitation treatment they receive

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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 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);

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Severe non-stroke related co-morbidity that may interfere with arm-hand function;

- Additional complaints that may interfere with the execution of the measurements;

- No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43425
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5848
NTR-old	NTR6027
CCMO	NL56494.015.16
OMON	NL-OMON43425

Resultaten