EXPLICIT-stroke

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1. Early rehabilitation intervention, i.e. Constraint Induced Movement Therapy (CIMT) or Elektromyography triggered neuromuscular stimulation (EMG-NMS), has a positive effect on functional outcome of upper limb paresis post stroke (A project) 2....

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

Samenvatting

ID

NL-OMON27283

Bron
NTR

Verkorte titel
EXPLICIT-stroke

Aandoening

cerebrovascular accident
stroke
beroerte

Ondersteuning

Primaire sponsor: ZON MW
Overige ondersteuning: ZON MW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- ARAT (A projects)
- Focussing of cortical activity in original target area (fMRI, B1 project)

- Integrity of corticospinal tract (TMS)
- Trunk movement in standard reaching task (B2 project)
- Neuromechanics, i.e. stiffness, motor function (paresis) and control (reflex gains and modulation) around wrist joint (B3 project)

Toelichting onderzoek

Achtergrond van het onderzoek

Prospective cohort studies show that about 80% of all stroke survivors have an upper limb paresis immediately after stroke. Only one third of all stroke patients will regain some dexterity, whereas well-researched evidence based therapies for effective treatment of the upper limb are lacking. However, the main claim of the literature is that functional recovery of the upper paretic limb is mainly defined within the first month post-stroke and that rehabilitation services should be applied preferably within this time window. Furthermore, it is known that exercise-related interventions are most effective when they are applied intensively and in a task-oriented way. EXPLICIT-stroke aims to obtain better functional outcome by early intensive rehabilitation. Next to clinical tests to measure improvement in function, neuroplasticity is assessed by fMRI, TMS, kinematics and haptic robots. The combination of clinical outcome measures and neuro-imaging will serve as a template for understanding basic mechanisms of functional recovery after stroke. EXPLICIT-stroke will provide an answer to the key question whether therapy induced improvements are due to either a reduction of basic motor impairment by neural repair or the use of behavioral compensation strategies.

Doel van het onderzoek

1. Early rehabilitation intervention, i.e. Constraint Induced Movement Therapy (CIMT) or Elektromyography triggered neuromuscular stimulation (EMG-NMS), has a positive effect on functional outcome of upper limb paresis post stroke (A project)

2. Observed therapy-induced changes in upper limb function can be related to changes in (sub)cortical reorganisation, corticospinal tract integrity, peripheral neuromechanics and compensation strategies (B project).

Onderzoeksopzet

15-09-2008: start inclusion of patients

31-12-2012: end of inclusion of patients

Onderzoeksproduct en/of interventie

group A1: good prognosis: Constraint Induced Movement Therapy (CIMT) for 3 consecutive

weeks, 5 days a week versus conventional therapy

group A2: poor prognosis:
Elektromyography-triggered neuromuscular stimulation (EMG-NMS) for 3 consecutive weeks, 5 days a week versus conventional therapy

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. First ever ischemic lesion in territory of MCA

2. Mono- or hemiparesis (NIHSS item 5a&b score 1-4)

3. Age 18-80

4. Able to comprehend and communicate

5. Able to sit for 30 s without support

6. Motivated to participate in an intensive rehabilitation treatment programme for 3 weeks

7. Written or oral informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Trombolysis (rTPA, alteplase) with positive effect

2. Pacemaker or metallic implants

3. Orthopaedic limitations of upper extremity

4. Not being able to communicate

5. Botuline toxine or medication that may influence upper limb function in previous 3 months.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-09-2008
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-08-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1366
NTR-old	NTR1424
Ander register	89000001 : ZON MW reg nr.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A