Gait therapy assisted by dual-channel functional electrical stimulation in early stroke rehabilitation: a proof-of-principle RCT

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Ten weeks of daily dual-channel functional electrical stimulation assisted gait training starting in the sub-acute phase after stroke is feasible and enhances gait efficiency compared to conventional gait training.

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

Samenvatting

ID

NL-OMON25761

Bron
Nationaal Trial Register

Verkorte titel
GAFESS

Aandoening

Keywords in English: FES, electric stimulation, stroke, gait disorders, rehabilitation

Keywords in Dutch: functionele elektrostimulatie, beroerte, gangbeeld lopen, spatiotemporele parameters, revalidatie

Ondersteuning

Primaire sponsor: AMC and Merem Rehabilitation Centre De Trappenberg
Overige ondersteuning: AMC and Merem Rehabilitation Centre De Trappenberg

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Gait symmetry (Stride length symmetry ratio)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Many patients after stroke suffer from pareses of lower extremity muscles, resulting in inefficient compensatory gait patterns and reduced walking ability. Functional electrical stimulation (FES) has been used to improve walking ability but evidence is limited. A recently developed device, the NESS L300™ Plus, is a lower extremity dual-channel FES (DFES) system, activating proximal as well as distal muscle groups of the lower extremity. Evidence for effectiveness in stroke rehabilitation is lacking. The use of DFES in the early gait rehabilitation after stroke may enhance gait efficiency.

Objectives: To investigate the feasibility and initial efficacy of a 10-week gait training with DFES during inpatient rehabilitation in the sub-acute phase after stroke on the recovery of spatiotemporal parameters, gait kinetics and kinematics, functional ambulation, walking ability and mobility.

Study design: A proof-of-principle controlled clinical trial.

Study population: Adult patients admitted for inpatient rehabilitation two to four weeks after the onset of stroke. 40 patients will be randomized to the intervention group (n=20) and control group (n=20).

Intervention: Additional to standard rehabilitation, subjects in the intervention group receive DFES-assisted gait training for one 30-minute session each workday, during maximal 10 weeks.

Primary outcome for efficacy is gait symmetry quantified by the stride length symmetry ratio).

Doel van het onderzoek

Ten weeks of daily dual-channel functional electrical stimulation assisted gait training starting in the sub-acute phase after stroke is feasible and enhances gait efficiency compared to conventional gait training.

Onderzoeksopzet

Baseline (T0), every two weeks (T1.1, T1.2, T1.3 and T1.4), stop intervention (T2), one month follow-up (T3) and three months follow-up (T4)

T1.1, T1.2, T1.4 and T3: only a selection of the secondary and other outcomes will be measured on this time points.

Onderzoeksproduct en/of interventie

Intervention group: Ten weeks, five days per week, one 30-minute gait therapy session a day (usual care) in which gait is assisted by functional electrical stimulation with a dual-channel device (NESS L300™ Plus).

Control group: usual care.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- clinical diagnosis of stroke (diagnostic criteria according to the World Health Organisation definition);

- In the sub-acute stage of stroke (within 31 days since stroke onset);

- age between 18 and 80 years old;

- referred to inpatient rehabilitation;

- medically stable and able to follow an intensive rehabilitation program;

- indication for gait training;

- sufficient power to stand in parallel bars with or without physical assistance;

- passive range of motion (PROM) ankle dorsiflexion of at least 0 degrees at full knee extension.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- subarachnoid hemorrhage;
- stroke in the cerebellum or brain stem;
- pre-existing lower extremity deficits or any other medical co morbidities that interfere significantly with gait, self reported maximum walking distance <300 meter or walking duration <6 minutes walking pre-stroke);
- severe cognitive problems or aphasia with severely impaired comprehension of test instructions;
- medical conditions that prevents participation or will lead to inability to comply with the protocol (e.g., congestive heart failure, patient receiving chemotherapy, uncontrolled epilepsy, pregnancy, depression or a psychotic disorder, etc.);
- a demand-type cardiac pacemaker, defibrillator or any electrical implant;
- a metallic implant at the affected lower extremity;
- a present or suspected cancerous lesion at the affected lower extremity;
- severe spasticity of the knee and ankle flexors and extensors (i.e., modified Ashworth Scale (mAS) ≥3)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	24-11-2014
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-08-2014
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	NL4611
NTR-old	NTR4762
Ander register	NL50002.018.14 : ABR

Resultaten