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

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25761

**Source**
NTR

**Brief title**
GAFESS

**Health condition**

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

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

### Sponsors and support

**Primary sponsor:** AMC and Merem Rehabilitation Centre De Trappenberg
**Source(s) of monetary or material Support:** AMC and Merem Rehabilitation Centre De Trappenberg

### Intervention

## Outcome measures

### Primary outcome

Gait symmetry (Stride length symmetry ratio)

### Secondary outcome

Spatiotemporal parameters (stance time, swing time, double support, swing:stance time, ratios, step length, stride length), EMG, Gait Assessment and Intervention Tool, Edinburgh Gait Score, Berg Balance Scale, comfortable Ten Meter Walking Test, Physiological Cost Index, Functional Gait Assessment, Functional Ambulation Categories, Timed Up and Go test, Six Minutes Walking Test, patient satisfaction

# Study description

### Background summary

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).

### Study objective

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.

### Study design

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.

### Intervention

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.

## Contacts


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# Eligibility criteria

## Inclusion criteria

- 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.

## Exclusion criteria

- 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)

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 24-11-2014 |
| Enrollment: | 40 |
| Type: | Actual |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

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|---|---|
| Date: | 28-08-2014 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL4611 |
| NTR-old | NTR4762 |
| Other | NL50002.018.14 : ABR |

# Study results