Effect of functional electrical stimulation of the ankle dorsiflexor muscles on the recovery of walking ability in patients with sub/postacute stroke.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22640

Source
Nationaal Trial Register

Brief title
FES-CVA

Health condition

stroke gait functional electrical stimulation

Sponsors and support

Primary sponsor: Erasmus medical center Rotterdam
Source(s) of monetary or material Support: Libra zorggroep (rehabilitation center) Eindhoven, Tilburg The netherlands

Intervention

Outcome measures

Primary outcome

1. 10m Walk Test (10MLT);

2. 6 minutes walk test (6MWT).

Secondary outcome

1. Berg Balance Scale (BBS);

2. Motricity Index of the lower extremities (MI);

3. Modified Ashworth Scale (MAS);

4. Functional Ambulation Categories (FAC);

5. Ankle movement; the maximum dorsiflexion of the ankle.

Study description

Background summary

This study is to identify the effects of a functional elektrical peroneal stimulation (FES) compared to ankle foot orthosis (AFO) on the recovery of walking ability in stroke patients with hemiparesis in the sub/ post-acute phase?

Study objective

There is no difference in het use of Functional electrical stimulation compared to the use of an ankle foot orthosis in the subacute / post-acute phase after stroke on the recovery of walking ability.

Study design

The participants were evaluated before and immediately after the training program.

Intervention

Participants are randomised to sessions of 30 minutes a day, 5 days a week, for 4 weeks of physiotherapy using either the FES walking aid or the AFO.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with a first stroke;

2. Subacute phase after stroke (between 4 weeks and 6 months after onset);

3. Age between 18-70 years;

4. Ischemic or hemorrhagic stroke;

5. Hemiparesis;

6. The passive range of motion of the dorsiflexor muscle of the ankle on the hemiparetic side is minimal 5 degrees;

7. Functional ambulation scale score 3.

Exclusion criteria

1. Cardiac or pulmonary disease that creates a contraindication for physical training;

2. On-demand pacemaker, defibrillator or any electrical or metal implant that could be influenced by the electrostimulation;

3. Malignant tumors;

4. Presence of a fracture or dislocation in the affected leg.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2012
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-03-2013
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	NL3716
NTR-old	NTR3879
Other	METC Erasmus MC : MEC-2012-021
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A