Clinical trial to compare electrical stimulation and the conventional ankle-foot orthosis (AFO) in the treatment of dropped foot following stroke

Submission date	Recruitment status	Prospectively registered
01/03/2001	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
01/03/2001	Completed	☐ Results
Last Edited	Condition category	Individual participant data
13/09/2016	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AP0770

Study information

Scientific Title

Clinical trial to compare electrical stimulation and the conventional ankle-foot orthosis (AFO) in the treatment of dropped foot following stroke

Study objectives

The aim of this study is to compare functional electrical stimulation (FES) with ankle foot orthosis (AFO) in the treatment of dropped foot following stroke.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Foot drop

Interventions

- 1. One group treated with AFO
- 2. Second group with electrical stimulation

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Walking speed (measured over 10 metres and timed by a stopwatch)
- 2. Physiological Cost Index (PCI)
- 3. Endurance (the total distance the participant is able to walk without an AFO or FES in 3 minutes)
- 4. Calf spasticity (measured using the modified Ashworth Scale)
- 5. Mobility (measured using the Rivermead Mobility Index)

Outcome measures were taken every six weeks.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1998

Completion date

31/12/2000

Eligibility

Key inclusion criteria

- 1. Single stroke of vascular origin in the last 6 months
- 2. Inadequate dorsiflexion during the swing phase of gait
- 3. May be a candidate for ankle-foot orthosis (AFO)
- 4. Able to walk 10 m
- 5. Willing to participate

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

22

Key exclusion criteria

- 1. Previous use of a dropped foot stimulator or AFO in four weeks prior to start of intervention
- 2. Required an AFO other than that selected for the trial

Date of first enrolment

01/01/1998

Date of final enrolment

31/12/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Medical Physics and Biomedical Engineering

Salisbury

United Kingdom

SP2 8BJ

Sponsor information

Organisation

Action Medical Research (UK)

Sponsor details

Vincent House Horsham West Sussex United Kingdom RH12 2DP

Sponsor type

Charity

Website

http://www.action.org.uk/

ROR

https://ror.org/01wcqa315

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration