

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

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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Department of Medical Physics and Biomedical Engineering

Salisbury

United Kingdom

SP2 8BJ

Sponsor information

Organisation

Action Medical Research (UK)

ROR

<https://ror.org/01wcqa315>

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary