ISRCTN72463123 https://doi.org/10.1186/ISRCTN72463123

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

Registration date
01/03/2001

Overall study status
Completed

Last Edited
13/09/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

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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