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

**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

## Study design
Randomised controlled trial

## Primary study design
Interventional

## 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**