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Strength training with Electrical Stimulation - is this a viable method of facilitating independent mobility and improving quality of life after a moderate to severe stroke?

Submission date
21/09/2009

Recruitment status
No longer recruiting

Registration date
28/09/2009

Overall study status
Completed

Last Edited
22/11/2019

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery supplying the brain (ischaemic stroke) or a bleed in the brain (haemorrhagic stroke). A large proportion of stroke victims suffer from long-term complications depending on the area of the brain that is affected, which can affect their ability to move, speak or even their cognitive function (memory loss, difficulty reasoning and confusion). One of the most common complications of a stroke is paralysis (hemiplegia) or weakness (hemiparesis) on one side of the body, particularly in the legs. It is important to start rehabilitation therapy as soon as possible after stroke as it gives patients the best chance of regaining their range of movement. Studies have shown however that even in patients who take part in active rehabilitation, the movement capabilities may never be restored. This can lead to patients not moving around as much and weakening of the muscles. Electrical stimulation is a technique in which the muscles and nerves are stimulated by pulses of electricity. This activation of muscles could help to prevent them from wasting away and even restore movement. The aim of this study is to find out whether electrical stimulation treatment can help to improve muscle strength and restore movement in stroke patients.

Who can participate?
Stroke patients under 80 years old who are unable to mobilise independently.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in six weeks of standard NHS therapy treatment combined with electrical stimulation treatment. This involves three sessions a week in which the muscles of the calf (gastrocnemius) and the front of the thigh (quadriceps) have a small electrical current applied to them. Those in the second group receive standard NHS therapy treatment only and are then monitored for six weeks. At the start of the study, and then again after 3 and 6 weeks, participants in both groups have their muscle strength and range of movement measured.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
March 2009 to August 2009

Who is funding the study?
Action Medical Research (UK)

Who is the main contact?
Dr Anand Pandyan

Contact information

Type(s)
Scientific

Contact name
Dr Anand Pandyan

Contact details
School of Health and Rehabilitation
Keele University
Staffordshire
United Kingdom
ST5 5GB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AP1131

Study information

Scientific Title
Strength training with Electrical Stimulation: a randomised controlled trial of a viable method of facilitating independent mobility and improving quality of life after a moderate to severe stroke

Study objectives
To develop a therapy protocol to prevent deterioration of muscle performance after a moderate to severe stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Manchester (Northwest 6- GM South) Research Ethics Committee approved on the 4th August 2008 (ref: 08/H1003/44)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
Treatment:
Six weeks treatment, three times per week with electrical stimulation on quadriceps, and gastrocnemius, combined with standard NHS therapy treatment.

Control:
Six weeks of monitoring progress after standard NHS therapy treatment.

There will be a measurement at the end of treatment but no further follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Muscle strength, measured at 0, 3 and 6 weeks

Secondary outcome measures
Measured at 0, 3 and 6 weeks:
1. Electromyography
2. Range of movement

3. Magnetic Resonance Imaging (MRI) of muscle volume
4. Ultrasound imaging for muscle architecture
5. Barthel Index
6. Nottingham Extended Activities of Daily Living (NEADL)
7. Visual analogue scale
8. Fatigue severity scale
9. Timed up and go
10. 10-metre walk

Overall study start date
01/03/2009

Completion date
20/08/2009

Eligibility

Key inclusion criteria
1. Below age of 80 years, either sex
2. Medically stable
3. Capable of providing informed consent
4. Patients who can sit and transfer independently, however who are unable to mobilise

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
10 acute stroke patients: 5 treatment, 5 control

Key exclusion criteria
Contraindication to electrical stimulation (i.e., orthopaedic implants at stimulation site, active cardiac implants, and skin reactions to electrodes)

Date of first enrolment
01/03/2009

Date of final enrolment
20/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University
School of Health and Rehabilitation
Newcastle
United Kingdom
ST5 5GB

Sponsor information

Organisation
Keele University (UK)

Sponsor details
School of Health and Rehabilitation
Staffordshire
England
United Kingdom
ST5 5GB

Sponsor type
University/education

Website
http://www.keele.ac.uk/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK) (ref: AP1131)

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