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Pilot study to investigate the effectiveness of combining physiotherapy and electrical stimulation to improve mobility in recently discharged stroke patients

Submission date
09/03/2007

Recruitment status
No longer recruiting

Registration date
16/07/2007

Overall study status
Completed

Last Edited
18/04/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
Version 1

Study information

Scientific Title
Pilot study to investigate the effectiveness of combining physiotherapy and electrical stimulation to improve mobility in recently discharged stroke patients

Acronym
EPIC - Electrical stimulation as Part of Integrated Physiotherapy

Study objectives
Electrical stimulation improves mobility, when delivered as an integrated part of outpatient physiotherapy for people less than 6 months post stroke.
This pilot study will investigate the use of electrical stimulation integrated into physiotherapy to improve gait in early stroke rehabilitation. The study will take place in a realistic clinical setting using techniques appropriate to a typical outpatient physiotherapy department. Stimulation will be applied to improve gait directly during walking. By using electrical stimulation in gait it is hoped to facilitate a more normal muscle activation pattern. It will also be used on various lower limb muscle groups as exercise to promote muscle strength, reduce antagonist spasticity and improve range of movement. During exercise and walking multiple muscle groups could be stimulated guided by the patient's particular problems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Wiltshire Ethics Committee (ref: 07/Q2004/19)

Study design
Randomised controlled pilot study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.salisburyfes.com/index2.htmReferral criteria and treatment protocol on: http://www.salisburyfes.com/pdfs/referral.PDF

Health condition(s) or problem(s) studied

Cerebral vascular accident/stroke

Interventions
A randomised controlled pilot study model will be used. 30 people who have had a stroke less than 6 months previously with a Rivermead Mobility Index score between 6 and 10 will be randomly assigned to a treatment or control group. The control group will receive physiotherapy appropriate to their needs while the treatment group will receive physiotherapy with the addition of electrical stimulation. All subjects will receive 2 physiotherapy sessions of duration 1 hour a week for 6 weeks. Subjects will be instructed in exercises to perform at home, which will include electrical stimulation in the treatment group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Walking speed over 10 m assessed at Week 1, Week 8 and Week 20. This has been shown to correlate well with more sophisticated measures of gait and is used routinely in the Salisbury Functional Electrical Stimulation Systems (FES) Clinic for comparison and audit purposes.

Secondary outcome measures
The following will be assessed at Week 1, Week 8 and Week 20:

Walking:
1. Effort as measured by Physiological Cost Index over 10 m. Polar heart rate monitor is used for non-invasive estimation of effort during the walking tests.
2. Visual gait analysis from video by blinded assessor using Rivermead Visual Gait Assessment from video when participants are able to walk sufficient distances. This measure should reflect changes in gait quality.

Function:
3. Six-minute walk. This simple test is suggested as way of quantifying change in walking ability with less floor or ceiling effects than walking tests over shorter distances. Six and 12 minute walks have been shown to be responsive to change and useful in documenting gait outcome over an inpatient stay.

Participation:
4. Canadian Occupational Performance Measure. This measures change in activities of daily living and assesses self-perceived satisfaction and performance. This outcome measure allows trial participants to focus on relevant personal problems and concerns.
5. Hospital Anxiety and Depression Scale, a widely used indicator of mood.
6. Rivermead Mobility Index to measure changes in mobility and to inform one of the selection criteria.

Overall study start date
15/04/2007

Completion date
15/04/2009

Eligibility

Key inclusion criteria
1. Participants will be over 18 years
2. Participants will be medically fit enough to undertake physiotherapy (consultant and GP approval will be sought prior to starting the trial)
3. Current inpatient stay will be for rehabilitation following first stroke
4. During the inpatient period participants will have demonstrated they have sufficient motivation, memory and cognitive ability to participate in treatment within physiotherapy and practice outside of treatment sessions
5. Patients will be able to understand spoken instructions
6. Participants' goals must include improving gait
7. Suitable patients will be returning home after hospital discharge with a Rivermead Mobility Index of between 6 and 10
8. Participants will be able to attend the hospital for twice weekly physiotherapy i.e. will have suitable transport and live within 25 miles of the hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Unable to tolerate sensation of stimulation (assessed prior to acceptance onto the trial)
2. Poor skin condition making stimulation unsuitable
3. Previous neurological conditions likely to influence response to treatment
4. Orthopaedic/other health problems limiting ability to participate or use stimulation /physiotherapy
5. Score of 25 or under on Mini Mental Test
6. Pacemaker and other active implant users
7. Poorly controlled epileptics
8. Pregnancy

Date of first enrolment
15/04/2007

Date of final enrolment
15/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The National Clinical Functional Electrical Stimulation Systems Centre
Salisbury
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Sponsor information

Organisation
Salisbury NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ja2ye75

Funder(s)

Funder type
Charity

Funder Name
Stroke Association (ref: TSA 2006/2007) (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No