ISRCTN77127531 https://doi.org/10.1186/ISRCTN77127531

Evaluation of the effects of chronic low frequency electrical stimulation on calf muscles in patients with intermittent claudication

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 05/04/2012	**Condition category** Circulatory System	

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
N0265126505

Study information

Scientific Title

Study objectives
1. Does a shuttle walk test of claudicants' functional capabilities detect improvements in calf muscle function resulting from treatment with chronic electrical stimulation for 4 weeks?
2. Will an intermittent programme (3 or 4 weeks intervention, 1 or 2 weeks non intervention) of chronic electrical stimulation of calf muscles in claudicants provide sustained improvements in calf muscle function and walking ability?
3. Does chronic electrical stimulation of calf muscles in claudicants and age-matched control subjects have vascular effects and improve nutritive circulation?

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)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Intermittent claudication

Interventions
In summary, eligible participants who have given informed consent will be familiarised with the testing procedures and equipment at the first visit. They will return after 1 week and be re-tested to give baseline values and then allocated to receive either an active muscle stimulator or a cutaneous nerve stimulator (TENS) as control. Two protocols for chronic stimulation are proposed to take account of patient availability for the duration of the study. One will use stimulators for 3 weeks at a time followed by a 1 week rest period. The other will use stimulators for 4 weeks at a time, followed by a 2 week rest period.

After stimulation at home for 3 periods of 20 minutes each day for either 3 or 4 weeks, participants will be reassessed. A rest period of 1 or 2 weeks will then be allowed followed by testing to establish whether any treatment-induced changes have reverted. Treatment - muscle stimulation or TENS - will then be resumed for a period of 3 or 4 weeks, followed by reassessment. After a further 1 or 2 week rest period, participants will undergo a final assessment which completes the study.

Participants in the study will therefore be required to attend on the following occasions:

1. Week 1 - Estimated duration 2 hr 30 min
As part of normal clinical evaluation at the Vascular Clinic prior to recruitment, a standard history will have been taken and general medical examination performed. Participants will be given a full explanation of the study including time to read the Patient Information Leaflet and the opportunity to ask any questions. Those who fulfil the selection criteria and give informed consent will be eligible to participate in the study. At the first visit for the study a treadmill test and shuttle walk test will be performed with full arterial assessment and a demonstration of the chair testing method will be given. After a 1 hour break with refreshments, the participants will undergo a formal assessment in the chair. During the break, the participant will be asked to complete the SF 36 questionnaire. Each participant will be issued with a physical activity logger device (a pedometer) and asked to wear it during the day throughout the following week. They will be invited to return after a period of 1 week for randomisation and commencement of treatment.

2. Week 2 - Estimated duration 3 hr
Participants will undergo a treadmill test and shuttle walk test with full arterial assessment. There will then be a period of rest for 1 hour with refreshments. Participants will then undergo a chair test. They will also undergo assessment of lower leg vascular function using venous occlusion plethysmography. Participants will then be randomised to a treatment group, either active (stimulation) or placebo (TENS). Following instruction in the use of the device they will be asked to commence treatment the next morning for a period of 3 or 4 weeks. Participants will be asked to hand in the activity logger used during the previous week and complete a Seven Day Physical Activity Recall questionnaire (PARQ). They will then be issued with another physical activity logger device and be asked to wear it during the day throughout the last week of stimulation.

3. Week 5 or 6 - Estimated duration 3 hr
Participants will undergo the full testing procedure (treadmill test, shuttle walk test, arterial assessment, chair test, vascular function test) as at week 2 and be asked to complete the SF 36 and PAR questionnaires. They will be instructed to cease treatment for a period of 1 or 2 weeks and proceed with normal daily activities.

4. Week 6 or 8 - Estimated duration 3 hr
Participants will undergo the testing procedure as at week 2 and 5/6 including the SF 36 questionnaire but excluding the shuttle walk test. They will be instructed to commence treatment as at week 2, either active muscle stimulation or TENS placebo, for a period of 3 or 4 weeks.

5. Week 9 or 12 - Estimated duration 2 hr 30 min
Participants will undergo the testing procedure as at week 6/8 (treadmill test, arterial assessment, chair test, vascular function test) including the SF 36 questionnaire.

6. Week 10 or 14 - Estimated duration 2 hr
Participants will undergo a testing session consisting of a chair test and vascular function test and SF36 questionnaire. They will then be discharged from the study.

The protocols used for assessment of walking ability (treadmill and shuttle walk test) and assessment of arterial status (ABPI5) are used routinely in patient assessment. Stimulators are routinely used in the treatment of patients with a variety of conditions.
The protocols for chair testing and assessment of vascular function (blood flow, capillary filtration capacity) are specifically for research purposes.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/06/2003

Completion date
27/06/2008

Eligibility

Key inclusion criteria
Patients with intermittent claudication who have been assessed in the Vascular Clinic at Selly Oak Hospital and who are not candidates for surgical intervention will be invited to participate in the study. Number of patients - up to 40. Inclusion criteria:
1. Sex - male and female
2. Age superior or equal to 40 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Up to 40

Key exclusion criteria

Not provided at time of registration

Date of first enrolment
27/06/2003

Date of final enrolment
27/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Vascular Surgery
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

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	01/02/2004		Yes	No