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The effects of electrical muscle stimulation in patients with chronic heart failure

Submission date	Recruitment status	[_] Prospectively registered
28/05/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/12/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2020	Circulatory System	

Plain English summary of protocol

Background and study aims

Exercise that increases heart rate reduces breathlessness, muscle weakness and improve exercise capacity in heart failure patients. However, those with advanced heart failure are so limited they cannot take more than a few steps without becoming breathless. They become housebound, depressed and often have a poor quality of life. They are currently unable to gain the social, physical and psychological benefits of exercise. Electrical Muscle Stimulation (EMS) involves attaching adhesive gel rubber electrodes (electrical conductor) to the large muscles of the legs, via an electrical cord to a battery operated controller. Regular EMS enhances muscle strength, so patients can start to perform more daily activities. At lower frequencies, EMS can also stimulate breathing and heart rate to the same level as light physical exercise. Research on exercise training has not included advanced heart failure patients who are often unable to exercise. These patients are not currently offered any non-medical options although potentially they could see increases in quality of life with small improvements in fitness. The aim of this study is to investigate whether eight weeks of lowfrequency EMS (LF-EMS) is tolerable and practical for patients with heart failure, and whether there is potential for enhancing their general level of physical activity with its associated health benefits.

Who can participate?

Adults with long term heart failure.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are treated with LF-EMS for eight weeks. This involves attaching adhesive electrodes to the large muscles of the legs which provide low level electrical impulses making the muscles gently twitch and contract for one hour, five times a week, for eight consecutive weeks. Those in the second group are given identical looking straps and electrodes, except that the simulation given is only enough to cause feeling in the skin and not enough to stimulate the muscles. At the start of the study and then after eight weeks and three months, participants in both groups have their exercise abilities assessed. In addition, they complete a questionnaire about their quality of life and have a heart and blood vessel scan.

What are the possible benefits and risks of participating?
Benefits include the opportunity to receive more interaction with health professionals which has been shown to be beneficial to short and long term health. There are no known risks to EMS, although some light muscular soreness may be experienced at first.

Where is the study run from?
1. University Hospital Coventry (UK)
2. Hospital of St. Cross, Rugby (UK)

When is the study starting and how long is it expected to run for?
April 2013 to September 2015

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Prithwish Banerjee
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Effects of continuous electrical muscle stimulation on exercise capacity, physical activity, cardiovascular function and quality of life in advanced heart failure patients: a pilot study study

Study objectives
The aim of this study is to investigate the effects of Low Frequency Electrical Muscle Stimulation (LF-EMS) on the leg muscles of severe chronic heart failure (CHF) patients on their fitness, heart and arterial health, activity level and quality of life after eight weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West midlands – Coventry & Warwickshire, 30/07/2013, ref: 13/WM/0240

Study design
Single blind parallel group randomised pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Heart failure

Interventions
Participants are randomised to one of two groups using a randomisation sequence using permuted block randomisation with concealed allocation from the outcomes assessor.

Intervention group: Participants are treated using Low Frequency – Electrical Muscle Stimulation (LF-EMS). Participants are asked to use the LF-EMS device for one hour, five times a week, for eight consecutive weeks. The duration of each session is 30 minutes initially, which progresses to one hour during the first two weeks as tolerance to the mild discomfort of LF-EMS improves. Of the five hourly sessions per week, four are completed unsupervised in the participant's own home and the other is conducted in a cardiac rehabilitation outpatient setting under the supervision of an exercise physiologist.

Control group: Participants are treated using a a sham device which looks identical to the LF-EMS and is programmed to deliver a very low level of stimulation (Frequency: 99Hz, pulse width: 150μs, maximum current amplitude: 7.3mA). This provides sensory input on the skin surface but

little or no muscle activation. Participants follow the same schedule as those in the intervention group.

All participants will undergo baseline testing before and after eight weeks of LF-EMS or sham placebo and again at 3 months follow-up.

Intervention Type
Device

Primary outcome measure
Exercise capacity is assessed by measuring maximal oxygen consumption (VO2peak) using spirometry and the 6 Minute walk Test (6MWT) at baseline, 8 weeks and 20 weeks.

Secondary outcome measures
1. Leg strength is measured using hand held dynamometer at baseline, 8 weeks and 20 weeks
2. Cardiac function is measured by 2D echocardiography and biomarker BNP at baseline and 8 weeks
3. Vascular function (arterial stiffness, and endothelial function) is measured using pules wave analysis and vascular ultrasound at baseline and 8 weeks
4. Physical activity is measured using sensewear activity armband at baseline, 8 weeks and 20 weeks
5. Quality of life is measured using the Minnesota Living with Heart Failure Questionnaire at baseline, 8 weeks and 20 weeks

Overall study start date
07/04/2013

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Able to provide written informed consent
2. Aged 18 years and over
3. Stable chronic systolic heart failure (LVEF < 40%) and NYHA class III-IV symptoms
4. Being treated within the University Hospital Coventry and Warwickshire NHS Trust
5. Established on reasonable standard treatment for heart failure (left ventricular systolic dysfunction)
6. Stable (defined as no hospital admission or alterations in medical therapy in the 2 weeks prior to inclusion)
7. Limited in their ability to perform exercise by either breathlessness or fatigue as a consequence of heart failure
8. Have had documented left ventricular systolic impairment on echocardiography

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Recruitment target of 60 and completion target of 40

Total final enrolment
60

Key exclusion criteria
1. Serious cardiac arrhythmias
2. Current neurological disorders or previous stroke with residual neurological deficit significant enough to limit exercise
3. Orthopaedic problems in hip or knee that prevent walking
4. Neuromuscular disease
5. Documented psychiatric problems, dementia or confusion
6. Very obese (those with mid-thigh circumference more than 50cm will not be able to wear the EMS straps)

Date of first enrolment
01/10/2013

Date of final enrolment
04/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Coventry
Clifford Bridge Road
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CV2 2DX

Study participating centre
Hospital of St. Cross, Rugby
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Sponsor information

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Sponsor type
Not defined

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Planned submission for publication in the European Journal of Preventative Cardiology (Sage).

Intention to publish date
31/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Chief Investigator Dr Prithwish Banerjee (prithwish.banerjee@uhcw.nhs.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	24/10/2013	05/12/2016	No	Yes
Results article	results	11/08/2017	17/12/2020	Yes	No
HRA research summary			28/06/2023	No	No