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Evaluating the benefits of a neuromuscular electrical stimulation (NMES) device in patients with intermittent claudication

Submission date
27/11/2017

Recruitment status
No longer recruiting

Registration date
28/11/2017

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Intermittent claudication (IC) is caused by a blockage in the artery of the leg, causing muscle pain. Although some evidence of the efficacy of neuromuscular electrical stimulation (NMES) in the management of patients with IC exists, further high quality research is required. This proposed study is vital to identify the contribution of clinical change using NMES, compared to the current gold standard recommended practice of supervised exercise therapy (SET) and, actual standard of care offered in the majority of the UK and Ireland, including best medical therapy (BMT). The device is expected to increase the walking distance in patients with intermittent claudication (IC), and therefore have a benefit on the same when provided in addition to supervised exercise programmes. It is also expected to cause a reduction in pain symptoms and reduced likelihood of major intervention in late stage peripheral arterial disease (PAD). The principal research objective is to assess the clinical efficacy of a neuromuscular electrical stimulation (NMES) device as an adjunct to the local standard care that is available at the study randomisation sites, in order to improve walking distance in patients with intermittent claudication (IC).

Who can participate?
Adults aged 18 and older who have IC.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard of care in which the treatment plan will be the same as those who decide not to enter the trial and will involve best medical therapy. Those in the second group are additionally provided with a NMES device and patients allocated to this arm are asked to use the device daily for a minimum of 30 minutes for a total period of 3 months thereafter. The device delivers electrical stimulation to create lower limb muscle contractions to improve circulation. Patients will complete diaries to record device usage and exercise attendance. Patients are invited back at 3 months, 6 months and 12 months.

What are the possible benefits and risks of participating?
The device is expected to have a direct benefit for patients with intermittent claudication. Previous studies show that the device increases blood flow in healthy people and it therefore it is expected to do the same for patients with intermittent claudication. The device has been through the national testing process and is safe to use for healthy individuals to improve circulation in the legs. The aim of this study is to look at its effect on people with Intermittent Claudication as the device has not been tested in these individuals. However, additional risks for this patient group are not anticipated.

Where is the study run from?
This study is being run by the Imperial College London (UK) and takes place in NHS trusts in the UK.

When is the study starting and how long is it expected to run for?
November 2017 to March 2021

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

Who is the main contact?
Miss Sasha Smith
sasha.smith@imperial.ac.uk

Study website
https://www.imperial.ac.uk/department-surgery-cancer/research/surgery/clinical-trials/nesic/

Contact information

Type(s)
Scientific

Contact name
Miss Laura Burgess

Contact details
Imperial College London
Section of Vascular Surgery
Room 14
4th Floor East Wing
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF
+44 0203 311 5208
l.burgess@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
NCT03446027

Secondary identifying numbers
CPMS 35485

Study information

Scientific Title
Does neuromuscular electrical stimulation improve the absolute walking distance in patients with intermittent claudication (nesic) compared to best available treatment? A multicentre randomised controlled study

Acronym
NESIC Version 1.0

Study objectives
The principal research objective is to assess the clinical efficacy of a neuromuscular electrical stimulation (NMES) device as an adjunct to the local standard care that is available at the study randomisation sites, in order to improve walking distance in patients with intermittent claudication (IC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Surrey REC, 20/11/2017, ref: 17/LO/1918

Study design
Randomized; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Participants meeting the eligibility criteria are randomised into two arms using a computer:
Arm 1 (Control): locally available therapy.
Arm 2 (Intervention): locally available therapy + NMES device

The locally available therapy comprises best medical therapy (BMT) and either exercise advice or supervised exercise therapy (SET), depending on the centre.

Patients randomised to the NMES device are advised to complete at least one pre-programmed 30-minute session daily, to a maximum of 6 sessions for 3 months and record usage in the compliance diary.

Treatment lasts for three months, with follow-up conducted at 3, 6 and 12 months thereafter.

Intervention Type
Other

Primary outcome measure
Absolute walking distance (AWD) is measured using treadmill testing at 3 months.

Secondary outcome measures
1. Initial claudication distance (ICD) is measured using treadmill testing at baseline, 3 month, 6 month and 12 months
2. Quality of Life (QoL) is measured using validated questionnaires (Intermittent Claudication Questionnaire (ICQ), EuroQoL 5D (EQ5D-5L), Short Form 36 (SF-36)) at baseline, 3 month, 6 month and 12 months
3. Haemodynamics are measured using Duplex ultrasonography*, Laser Doppler Flowmetery (LDF) and Ankle Brachial Pressure Index (ABPI) at baseline, 3 month, 6 month and 12 months
*performed at baseline and 3 months only.
4. Health economic assessment is measured using validated QoL questionnaires and compliance data at baseline, 3 month, 6 month and 12 months
5. Compliance with interventions is measured using patient compliance diaries and data loggers at 3 months
6. Device experience questionnaire is measured using patient device experience questionnaire at 3 months

Overall study start date
01/11/2017

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Capacity to provide informed consent
2. Aged 18 years or above

3. Positive Edinburgh Claudication Questionnaire
4. ABPI <0.9 OR positive stress test (fall in ankle pressure >30mmHg, 40 secs post 1 min treadmill at 10% gradient, 4 km/h)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 192; UK Sample Size: 192

Total final enrolment
200

Key exclusion criteria
1. Severe IC requiring invasive intervention as determined by the treating clinician
2. Critical limb ischaemia as defined by the European Consensus Document
3. Co-morbid disease prohibiting walking on a treadmill or taking part in supervised exercise therapy.
4. Popliteal Entrapment Syndrome
5. Commenced vascular symptom specific medication in previous 6 months e.g. naftidrofuryl oxalate, cilostazol
6. Pregnancy. Participants must be of non-childbearing potential* OR using adequate contraception for the duration of the study period and have a negative urine pregnancy test result
7. Any implanted electronic, cardiac or defibrillator device
8. Acute Deep Vein Thrombosis
9. Broken or bleeding skin including leg ulceration
10. Peripheral neuropathy
11. Recent lower limb injury or lower back pain

* defined as those who have no uterus, ligation of the fallopian tubes, or permanent cessation of ovarian function due to ovarian failure or surgical removal of the ovaries. A woman is also presumed to be infertile due to natural causes if she has been amenorrheic for greater than 12 months and has an FSH greater than 40 IU/L

Date of first enrolment
15/01/2018

Date of final enrolment
20/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. Marys Hospital
Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
University Hospitals Bristol Nhs Foundation Trust
Marlborough Street
Bristol Avon
United Kingdom
BS1 3NU

Study participating centre
Hull Royal Infirmary
Hull And East Yorkshire Hospitals NHS Trust
Anlaby Road
Hull North Humberside
Hull
United Kingdom
HU3 2JZ

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Mailpoint 18
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre

Addenbrookes Hospital
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Freeman Hospital
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle Upon-Tyne
United Kingdom
NE7 7DN

Study participating centre
Musgrove Park Hospital
Taunton And Somerset NHS Foundation Trust
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Queens Medical Centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Imperial College of Science, Technology and Medicine

Sponsor details
Kensington
London

England
United Kingdom
SW7 2AZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/041kmwe10

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
1. Planned publication and presentation of results at scientific meetings
2. Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion)
3. There will also be an online dissemination plan, with participants and healthcare professionals able to access results on a trial website, and appropriate use of social media (Twitter, Facebook, LinkedIn)
4. Trial participants will also be offered a mailed summary of the trial findings

Intention to publish date
05/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2019	08/03/2021	Yes	No
HRA research summary			26/07/2023	No	No
Results article		25/09/2023	26/09/2023	Yes	No
Results article		01/07/2023	21/01/2025	Yes	No