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Effects of electrical stimulation of the calf muscle using a new textile electrode setup on blood flow and discomfort

Submission date	Recruitment status	[_] Prospectively registered
07/01/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/01/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/05/2023	Circulatory System	

Plain English summary of protocol

Background and study aims
The formation of unwanted blood clots in the veins of the legs is a serious and potentially fatal health problem. Unwanted blood clots in legs can occur as the result of reduced mobility (due to surgery, stroke, injuries, etc), an increased tendency for blood clotting (due to cancer, inherited conditions, etc), and other factors. Neuromuscular electrical stimulation systems (NMES) deliver electrical impulses through electrodes to the skin over muscles to cause muscle contraction. A new textile electrode integrated into socks could give the patient better mobility and better compliance with treatment. The aim of this study is to compare the effects of reusable textile electrodes and traditional NMES-gel electrodes on blood flow and discomfort in healthy volunteers.

Who can participate?
Healthy volunteers aged 18-75 years

What does the study involve?
Participants receive calf electrical stimulation with a set of standard gel electrodes and with a set of textile electrodes integrated into socks. Participants' blood flow will be measured before and during the intervention with an ultrasound of the veins in the knee crease and the groin. Participants will rate their experience of discomfort during the stimulation.

What are the possible benefits and risks of participating?
The short-term NMES treatment tested is not expected to have any benefits or risks for the participants. The participant can withdraw from the study at any time.

Where is the study run from?
Karolinska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2019 to October 2021

Who is funding the study?
The study is funded by the strategic innovation programs Swelife and Medtech4Health, which are jointly arranged and funded by Sweden´s Innovation Agency (Vinnova), Formas and Energimyndigheten.

Who is the main contact?
Prof. Paul Ackermann
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-05479

Study information

Scientific Title
Effects of calf neuromuscular electrical stimulation on hemodynamics and discomfort using a new textile electrode setup

Study objectives

It is hypothesized that a new textile electrode would result in non-inferior hemodynamics and comfort compared to a standard motor point electrode setup of gel electrodes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/01/2020, Etikprövningsmyndigheten (Box 2110, 750 02 Uppsala, Sweden; +46 (0)10 475 08 00; etikprovning.se), ref: 2019-04020

Study design
Interventional non-blinded randomized cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Deep vein thrombosis

Interventions
The total time for the intervention including set-up and testing for motor points is 2 hours. Patients are randomized to receive standard treatment or textile electrode treatment first. The wash-out period between the two treatments is 1 week.

The intervention is textile electrodes integrated into socks, designated as the transverse textile electrode (TTE) setup, consisting of two rectangular textile electrodes (2 x 2.5 cm) transversally woven into the back of a sock (Polyamide/Lycra blended yarn). The electrodes are placed approximately at the largest circumference of the calf, and with the electrodes inner edges equally distanced from the midline of the calf approximately 2 cm apart. The electrodes are woven into the sock using intarsia knitting which allows for seamless integration of patterns of functional components in a single process. The material of the electrodes is silver coated polyamide multifilament yarn with the trade name Shieldex® (produced by Statex Produktions und Vertriebs GmbH).

The intervention is compared to commercially available standard adhesive gel electrodes (Compex Snap, Performance, DJO Global, USA, 5 x 5 cm) manually trimmed to squares sized 3 x 3 cm to reduce the current intensity needed to induce a muscle response. The standard electrodes

are placed on the skin areas of the calf, one on the medial side and one on the lateral side, that required the least NMES current intensity to trigger a calf muscle response, i.e. the “best” motor points (MP). This electrode setup is designated the motor point electrode (MPE) setup.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
Shieldex®

Primary outcome measure
Peak venous velocity in vena poplitea measured using Doppler ultrasound (CX50, Philips Medical Systems, Andover, MA, USA) during baseline and on three occasions during a 5-minute neuromuscular electrical stimulation of the calf

Secondary outcome measures
Peak venous velocity in vena femoralis measured using Doppler ultrasound (CX50, Philips Medical Systems, Andover, MA, USA) during baseline and on three occasions during a 5-minute neuromuscular electrical stimulation of the calf

Overall study start date
01/01/2019

Completion date
10/10/2021

Eligibility

Key inclusion criteria
Healthy volunteers aged 18-75 years

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants

10

Total final enrolment
10

Key exclusion criteria
1. Pregnancy
2. Skin ulcers
3. Previous surgery on blood vessels of the lower limbs
4. Pacemaker
5. Intracardiac defibrillator
6. Advanced heart disease
7. Kidney failure
8. Neuromuscular or metabolic disease

Date of first enrolment
10/01/2020

Date of final enrolment
20/01/2021

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska University Hospital
Akademiska Stråket 13
Solna
Sweden
17164

Sponsor information

Organisation
Karolinska University Hospital

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Eugeniavägen 3, Solna
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Sponsor type
Government

Website
https://www.karolinska.se/en/karolinska-university-hospital/about-karolinska/contact-and-visit-us/

ROR
https://ror.org/00m8d6786

Funder(s)

Funder type
Government

Funder Name
VINNOVA

Alternative Name(s)
Swedish Governmental Agency for Innovation Systems

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Svenska Forskningsrådet Formas

Alternative Name(s)
Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning, Swedish Research Council Formas, Formas

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Energimyndigheten

Alternative Name(s)
Swedish Energy Agency, egentligen Statens energimyndighet, STEM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Publication and dissemination plan
The results are planned for publication in a high-impact peer-reviewed journal.

Intention to publish date
10/04/2022

Individual participant data (IPD) sharing plan
Raw data will be available from the researchers on reasonable request.
What data will be shared: All the individual participant data collected during the trial, after deidentification.
What other documents: Patient information, study protocol.
When: Immediately following publication and ending 5 years following publication.
With whom: Researchers who provide a methodologically sound proposal.
For what: To achieve the aims in the approved proposal.
By what mechanisms: Proposals should be directed to Robin Juthberg (robin.juthberg@ki.se).
Requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			11/01/2022	No	Yes
Protocol file			11/01/2022	No	No
Preprint results		18/01/2022	20/12/2022	No	No
Results article		05/05/2023	09/05/2023	Yes	No