

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

Submission date 07/01/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/05/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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
paul.ackermann@ki.se

Contact information

Type(s)

Principal investigator

Contact name

Prof Paul Ackermann

ORCID ID

<https://orcid.org/0000-0002-5520-169X>

Contact details

Department of Trauma, Acute Surgery and Orthopedics
Karolinska University Hospital
Stockholm
Sweden
17176
+46 (0)8 517 700 00
paul.ackermann@ki.se

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

Completion date

10/10/2021

Eligibility

Key inclusion criteria

Healthy volunteers aged 18-75 years

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

75 years

Sex

All

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

ROR

<https://ror.org/00m8d6786>

Funder(s)

Funder type

Government

Funder Name

VINNOVA

Alternative Name(s)

Swedish Governmental Agency for Innovation Systems, Vinnovase

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)

The Swedish Energy Agency, Swedish Energy Agency (SWEA), Swedish Energy Agency, egentligen Statens energimyndighet, STEM

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Results and Publications

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?
Results article		05/05/2023	09/05/2023	Yes	No
Participant information sheet			11/01/2022	No	Yes
Preprint results		18/01/2022	20/12/2022	No	No
Protocol file			11/01/2022	No	No