ISRCTN12112819 https://doi.org/10.1186/ISRCTN12112819

Electrical Stimulation treating knee osteoarthritis for pain, function and strength

Submission date	Recruitment status	[X] Prospectively registered
28/03/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/05/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/10/2024	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Osteoarthritis of the knee is a common joint condition causing pain, stiffness and weakness around the knee joint. A new device has been developed to reduce pain levels and improve strength in the calf and quadriceps. The aim of the study is to investigate whether a neuromuscular stimulation device can produce an improvement in strength, pain, exercise capacity and health-related quality of life compared to a sham device.

Who can participate?
People with diagnosed knee osteoarthritis who are over the age of 45 and under the age of 85. Due to the use of electrical stimulation, there are some reasons which would stop you being able to take part in the study, these are listed below.
1. Fitted with an electronic implant such as a pacemaker or defibrillator
2. Pregnant
3. Existing or undergoing treatment for Deep Vein Thrombosis
4. Inflammatory arthritis
5. Dermatological conditions affecting the feet or legs
6. Neurological disorder affecting the feet or legs
7. Significant osteoarthritis of the hip, ankle or foot
8. Current or recent knee surgery trauma or injury in the last 3 months
9. Had a total knee replacement, partial knee replacement or high tibial osteotomy on the knee to be studied
10. Previous corticosteroid or hyaluronic acid injections in the last 6 months
11. Body Mass Index over or equal to 40 kg/m²
12. Currently attending physiotherapy
13. Use of TENS
14. Use of Neuromuscular stimulation device or ‘Revitive’ device
15. Significantly impaired cognitive ability
16. Unable to mobilise
17. Inability to provide informed consent

What does the study involve?
If you are suitable for the study you will be provided with an activity monitor to wear for 1 week

prior to using the device. The following week you will return to the Glenfield Hospital for approximately 2 hours. This will involve measuring muscle strength, exercise tolerance and completing some questionnaires. You will then be randomised into either a group that receives a working device, or a control group that receives a 'sham' device. You will use the device once per day for 8 weeks at home, with each session lasting between 30 and 50 minutes. After 4 weeks you will be contacted by a member of the clinical team to find out how you are getting on using the device. After 7 weeks you will be sent an activity monitor to track your activity levels over the final week of the study. After 8 weeks you will be invited to come back to Glenfield Hospital for a third visit where muscle strength and exercise tolerance will again be measured, and the same questionnaires will be completed.
8 weeks after your final study visit you will be sent the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire through the post to complete.

What are the possible benefits and risks of participating?
We do not anticipate any serious risks. The device has been through rigorous testing processes, including previous clinical trials, and has a CE mark for use in patients with osteoarthritis. Activation of the muscles might result in an odd sensation at first but it should not hurt. There are several levels of intensity meaning that the device can be adjusted for your comfort.

We know from previous studies that the Revitive device increases blood flow and alleviates swelling in patients and healthy individuals. We expect it to be of direct benefit to you if you suffer from pain, stiffness and swelling or weakened leg muscles. You will not get paid for participating in this study.

Where is the study run from?
Centre of Exercise and Rehabilitation Sciences, Glenfield Hospital, Groby Road, Leicester, LE3 9QP.

When is the study starting and how long is it expected to run for?
January 2017 to September 2022

Who is funding the study?
Actegy Ltd

Who is the main contact?
Samuel Briggs-Price
Samuel.briggs-price@uhl-tr.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Samuel Briggs-Price

ORCID ID
https://orcid.org/0000-0001-7435-3173

Contact details

Biomedical Research Centre - Respiratory
Glenfield Hospital, Groby Road
Leicester
United Kingdom
LE3 9QP
01162502758
samuel.briggs-price@uhl-tr.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
8

Study information

Scientific Title
A double blind, randomised, sham-controlled trial investigating the effects of combining electrical stimulation of the calf and thigh muscles in patients with osteoarthritis of the knee

Acronym
SKOPE

Study objectives
1. Patients training with an electrical stimulation device for 8 weeks will have a reduction in pain and an improvement in strength compared to a sham device
2. Patients training with an electrical stimulation device for 8 weeks will show improvements in quality of life measures and functional performance compared to a sham device

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2017, North West- Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ; nrescommittee.northwest-preston@nhs.net; 0207 104 8234), ref: 17/NW/0081.

Study design
Single-centre randomised control trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
Participants are randomised by a computer-generated system to one of two groups:
1. Revitive device
2. Sham device
This will be a blinded study, therefore, participants will not know which device they will receive until the end of the study. The assessor will also be unaware of this.

The Revitive device is an electrical stimulation device comprising of a foot plate and gel pad electrodes. Muscular contraction is stimulated in the calf through the footplate and in the quadriceps by placing the gel pads on the skin. The intensity of stimulation is controlled through a remote by the participant. The sham device will be identical including the remote control, although the device will provide insufficient stimulation to achieve muscular contraction.

The participants will require three visits to the hospital in total. The first visit will provide further information for the study, obtain consent, provide activity tracker and collect medical and demographic details. On the second visit participants will perform strength testing, functional tests and questionnaires. They will also be randomized to the device or sham device on the second visit, this will be performed by another researcher through sealedenvelopes.com. The footplate will be used daily for 30 minutes. The quadriceps electrodes will be used 5 times a week for 20 minutes. A participant diary will be kept to log intensity and frequency of use. After 7 weeks the participants will be sent an activity tracker to wear during the final week. After 8 weeks the initial measures will be repeated and this will conclude the visit schedule. Those on the sham treatment will be offered the real device.

(added 19/05/2022): 8 weeks after the final study visit participants will be sent the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire through the post to complete.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Current primary outcome measure as of 13/05/2022:
The pain domain of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire. The primary end point of the trial is week 8.

Previous primary outcome measure:
Osteoarthritis is measured using The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at week 1 and week 8.

Key secondary outcome(s))
Current secondary outcome measures as of 13/05/2022:
1. Self-Reported Knee Pain, Function and Stiffness is measured by the WOMAC and Oxford Knee score
2. Health status will be measured by the 36-Item Short Form Survey (SF-36), EuroQol 5-Dimension 5-Level health questionnaire (EQ-5D-5L), Medical Outcome Study Sleep Scale (MOS Sleep) and Hospital Anxiety and Depression Score (HADS)
3. Muscle strength will be measured by means of isokinetic dynamometer at week 1 and week 8.
4. Swelling will be measured through joint line circumferences of the knee and ankle at week 1 and week 8.
5. Pain at rest and during movement will be measured using the visual analogue scale (VAS) at week 1 and week 8.
6. Physical activity will be measured using accelerometers worn around the waist at week 0 and week 7.
(added 19/05/2022)
7. Functional performance is measured via the incremental shuttle walk (ISWT), endurance shuttle walk (ESWT)and the short performance physical battery (SPPB) at week 1 and week 8

Previous secondary outcome measures:
1. Health-related quality of life is measured via the Oxford Knee Score, EQ-5D, SF-36 and Pittsburgh sleep quality index at week 1 and week 8.
2. Functional performance is measured via the incremental shuttle walk (ISWT), endurance shuttle walk (ESWT)and the short performance physical battery (SPPB) at week 1 and week 8.
3. Muscle strength will be measured by means of isokinetic dynamometer at week 1 and week 8.
4. Swelling will be measured through joint line circumferences of the knee and ankle at week 1 and week 8.
5. Pain at rest and during movement will be measured using the visual analogue scale (VAS) at week 1 and week 8.
6. Physical activity will be measured using accelerometers worn around the waist at week 0 and week 7.

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. OA diagnosed clinically in accordance with NICE guidance.
2. Aged 45-85 years.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Fitted with an electronic implant such as a pacemaker or defibrillator.
2. Pregnant.
3. Existing or undergoing treatment for DVT.
4. Significantly impaired cognitive ability.
5. Inflammatory arthritis.
6. Dermatological conditions affecting the feet or legs.
7. Neurological disorder affecting the feet or legs.
8. Significant osteoarthritis of the hip, ankle or foot.
9. Current or recent knee surgery, trauma or injury (last 3 months).
10. Previous corticosteroid or hyaluronic acid injections (last 6 months).
11. BMI over 40.
12. Use of transcutaneous electrical stimulation.
13. Use of neuromuscular electrical stimulation device.

Date of first enrolment
20/05/2019

Date of final enrolment
30/05/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Glenfield Hospital, University Hospitals of Leicester,
Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
Actegy Ltd

Funder(s)

Funder type

Industry

Funder Name
Actegy Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/08/2022	26/08/2022	Yes	No
Basic results			28/10/2024	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	version V4	03/04/2019	23/05/2019	No	Yes
Participant information sheet	version 5	11/10/2019	12/08/2021	No	Yes