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Electrical stimulation in diabetic peripheral neuropathy

Submission date
18/03/2015

Recruitment status
No longer recruiting

Registration date
20/03/2015

Overall study status
Completed

Last Edited
14/08/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Peripheral neuropathy is the name given for a group of conditions in which the nerves of the peripheral nervous system are damaged. Symptoms include numbness, tingling, burning, stabbing and shooting pain in the affected areas, problems with balance and co-ordination and muscle weakness (particularly in the feet). It most commonly affects the arms and legs and often affects people with diabetes (20-50%). It has a major impact on day to day living, and treatments for it are currently limited to pain control. A new device, Geko™ , has been developed that might mimic the effect of exercise. This has been shown to help to slow down progression of peripheral neuropathy.
The device is about the size of a man's wrist watch and when attached to the leg and switched on it produces gentle electrical impulses. These impulses cause the calf muscle pumps to twitch, and it is this twitching that increases the flow of blood in the lower legs – mimicking the blood flow normally achieved by walking but without having to move or exert energy. We believe it is this increased blood flow to the leg nerves that will help the symptoms of peripheral neuropathy. The aim of this study is to see whether Geko™ can alleviate or cure diabetic peripheral neuropathy.

Who can participate?
Adults (at least 18) with type 2 diabetes and peripheral neuropathy.

What does the study involve?
The study lasts 10 weeks. Participants are required to attend Charing Cross Hospital a total of 2 times, and each visit will last around 1 hour. During the first visit participants have a medical history and examination taken by a doctor. They are asked about and are tested for other things that can cause similar problems in leg nerves (such as high alcohol intake, HIV, and syphilis). Any positive findings are discussed with the participant directly by a doctor on the team. We can then discuss with them what they would like done with that information. The participant in question would not be able to participate in the trial beyond this point. Eligible participants then have an ultrasound scan of their legs, and they are then randomly allocated into one of two groups. Those in group 1 wear the Geko™ device every day for ten weeks. Those in group 2 do not wear a device. We look at the nerve test of each participants legs measured at the start of the study, and repeat this at the end of the study. We compare the two groups to each other.

Participants have blood (around 10ml/1 tablespoon) and urine samples taken at the beginning and end of the study (2 times in total), for us to look at markers of blood vessel function and clotting. In between visits to the hospital each participant in group 1 is given a supply of devices that we would like them to wear every day for 4 or more hours per day. They are asked to keep a diary of how long each device is activated for, and how comfortable they find the device. We ask each participant to let us know if they become unwell, or get admitted to hospital for any reason. We also ask them to fill in a quality of life questionnaire at the beginning and end of the study.

What are the possible benefits and risks of participating?
We know from previous studies that the Geko™ device increases blood flow in healthy people. We expect it to do the same for participants, including the blood supply to the nerves in their leg. There may be a positive effect on their peripheral neuropathy, although we do not know yet if this will be the case. We can provide participants with a taxi ride to and from the department when they attend. We do not anticipate any risk. The device has been through the national testing process and has a CE mark. Its use in this study is under licence. The product is not licensed for use in pregnancy. Female participants interested in our study have to undergo a urinary pregnancy test before progressing any further. Women who are pregnant or planning a pregnancy should not take part. Activation of the device causes small impulses to travel through the skin to make the foot and calf twitch. It may be an odd sensation but should not hurt. In the past some people have had a skin reaction to the jelly used to apply the device to the leg. If this happens we recommend using a slightly different application site for the device to give the skin a rest.

Where is the study run from?
Charing Cross Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2014 to June 2015

Who is funding the study?
Imperial College London (UK)

Who is the main contact?
Miss Katherine Williams

Contact information

Type(s)
Scientific

Contact name
Miss Katherine Williams

ORCID ID
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Contact details
Charing Cross Hospital
NHLI
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W6 8RP

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02082145

Protocol serial number
18415

Study information

Scientific Title
Electrical stimulation in diabetic peripheral neuropathy: a randomised controlled trial

Acronym
NERVES

Study objectives
We are studying the effect of a medical device which enhances blood flow in the legs. We have seen cases where diabetics have found some relief from pain in their legs whilst using the device. We postulate that this device may modify or reverse diabetic peripheral neuropathy - therefore we are carrying out a clinical trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Dulwich, 31/01/2014, ref: 13/LO/1844

Study design
Randomised; Interventional; Design type: Process of Care, Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes; Subtopic: Both; Disease: Neuropathy, Diabetic Control, Device studies, Diabetic foot

Interventions
Geko device: Small self-adhesive neuromuscular stimulator, applied to the skin
Study Entry : Single Randomisation only

Intervention Type
Device

Primary outcome(s)
Nerve conduction testing; Timepoint(s): Week 0 and week 10

Key secondary outcome(s))
1. Disease specific and generic quality of life questionnaires, week 0 and week 10
2. Blood and urine for metabolic profiling, week 0 and week 10

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. 18+ years old
2. Diabetes as defined by WHO diagnostic criteria on best medical therapy
3. Diabetic peripheral polyneuropathy present, confirmed by nerve conduction testing
4. Both genders
5. Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Pacemaker
3. Metal implants in the legs (below knee)

Date of first enrolment
01/10/2014

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Charing Cross Hospital
NHLI
The Reynolds Building
St. Dunstans Road
London
United Kingdom
W6 8RP

Sponsor information

Organisation
Imperial College Healthcare NHS Trust

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Government

Funder Name
Imperial College London

Alternative Name(s)
Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			14/08/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes