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Does the Geko nerve stimulator reduce Deep Vein Thrombosis (DVT) and improve healing in ankle fractures?

Submission date
17/07/2012

Recruitment status
Stopped

Registration date
07/01/2013

Overall study status
Stopped

Last Edited
20/05/2016

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There has been a recent trend amongst athletes to use peroneal (leg) nerve stimulators to reduce swelling after training or competition. The Geko peroneal nerve stimulator is a piece of equipment that sits on the skin at the side of the leg and sends electrical impulses through the skin so that the leg muscles can be stimulated to different levels. There is evidence that these nerve stimulators reduce the rates of leg clots and improves the circulation to the leg. The aims of this study are to find out if the Geko peroneal nerve stimulator reduces the rate of leg clots and improves the bone healing in patients who have had their ankles fixed after fracture.

Who can participate?
Adults both male and female, with closed ankle fractures who present to Wirral University Hospital.

What does the study involve?
The study participants would be approached by a member of the clinical team and the research team and then after the appropriate consent is obtained, they would be included into the trial. Each patient would then be randomised into one of two groups i.e. those who receive the stimulator for a two week period post operative period and those who do not. The treatment of patients will not be affected by this trial. Patients in the treatment group would receive the stimulator for 2 weeks after being counselled by the research team. At the normal two week follow up patients in both groups will have their leg circumference measured and a vascular ultrasound performed to exclude the presence of a leg clot. Normal follow up is then at the six week period where X rays are taken and leg circumference is yet again measured. At the three month period patients answer a questionnaire.

What are the possible benefits and risks of participating?
The benefits of participating in the study would include a reduction in post operative swelling, time to healing and rates of leg clots. The possible risks include minor discomfort from the stimulator or allergic reaction to the stimulator pad, a delay in healing of the bone.

Where is the study run from?
Wirral University Teaching Hospital (UK)

When is the study starting and how long is it expected to run for?
The study started in November 2012 and is expected to run until we have enough patients in each group or run out of Geko stimulators.

Who is funding the study?
The study is being funded by Wirral University Hospital primarily. Skymed Limited are providing the Geko stimulators for free and we are applying from external funding from the British Orthopaedic Foot and Ankle Association (BOFAS) for the ultrasound funding.

Who is the main contact?
1. Mr Michael Hennessy (Consultant Orthopaedic Surgeon), mchenno@btinternet.com
2. Mr Peter Kenyon (Specialist Registrar), dr_kenyon@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Mr Michael Hennessy

Contact details
Wirral University Teaching Hospital
Arrowe Park Road
Upton
Wirral
Merseyside
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CH49 5PE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12/NW/0083

Study information

Scientific Title
A randomised controlled trial investigating the effect of the Geko nerve stimulator to reduce DVT rates and improve healing in ankle fractures

Study objectives
The null hypothesis is that there is no alteration in the rates of DVT or the time to clinical and radiological union following open reduction and internal fixation of the ankle when using the Geko peroneal nerve stimulator.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Liverpool Central, 02/04/2012, ref: 12/NW/0083

Study design
Randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Ankle fracture

Interventions
Each patient randomised into one of two groups i.e. those who receive the stimulator for a two week period post operative period and those who do not.

The treatment of patients will not be affected by this trial. Patients in the treatment group would receive the stimulator for 2 weeks after being counselled by the research team. At the normal two week follow up patients in both groups will have their leg circumference measured and a vascular ultrasound performed to exclude the presence of a leg clot. Normal follow up is then at the six week period where x rays are taken and leg circumference is yet again measured. At the three month period patients answer a Manchester - Oxford Foot and Ankle Questionnaire.

Intervention Type
Device

Primary outcome measure
1. DVT rate
2. Time to Union

Secondary outcome measures
1. Manchester - Oxford Foot and ankle questionnaire at end of 3 months
2. Time to return work

Overall study start date
01/11/2012

Completion date
01/11/2013

Reason abandoned (if study stopped)
Trial did not start

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older, either sex
2. Patients with closed ankle fractures that have required open reduction and internal fixation
3. Patients who are able to consent for themselves

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Open fractures
2. Diabetics
3. Those with peripheral neuropathy, metabolic bone disorders and immunological disorders
4. Patients undergoing revision procedures
5. Patients with syndesmotic injury requiring screw removal prior to mobilisation
6. Those unable to use the Geko device

Date of first enrolment
01/11/2012

Date of final enrolment
01/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wirral University Teaching Hospital
Merseyside
United Kingdom
CH49 5PE

Sponsor information

Organisation
Wirral University Teaching Hospital (UK)

Sponsor details
Arrowe Park Road
Upton Wirral
Merseyside
England
United Kingdom
L176GD

Sponsor type
Hospital/treatment centre

Website
http://www.whnt.nhs.uk

ROR
https://ror.org/05cv4zg26

Funder(s)

Funder type
Industry

Funder Name
Skymed Ltd (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration