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Keele University

Intercalation Research Project

Project Title:	The effectiveness of the geko™ device to prevent deep vein thrombosis in immobile acute stroke patients.
Lead Supervisor **Name:** **Department:** **Email Address:** **Telephone:**	 Professor Christine Roffe Institute for Science and Technology in Medicine christine.roffe@northstaffs.nhs.uk 0300 123 1465
Co-supervisor **Name:** **Department:** **Email Address:** **Telephone:**	 Dr Tracy Nevatte Institute for Science and Technology in Medicine tracy.nevatte@northstaffs.nhs.uk 0300 123 0891

Aims

Please outline the aims of your proposal (250 words):

This is part of a wider program of research of which the overall aim is to investigate whether the geko™ device prevents deep vein thrombosis (DVT) in immobile stroke patients. The program will also investigate the rehabilitation of stroke patients who use the geko™ device. The geko™ device provides Neuromuscular Electrostimulation (NMES) of the peroneal nerve. It is currently used to increase blood circulation, prevent DVT, prevent and treat oedema, promote wound healing and promote healing of tendon and ligament injuries. The geko™ device has not been studied in stroke patients so a feasibility study is required to inform the larger randomised controlled trial (RCT).

Research question: what is the feasibility of using the geko™ device to reduce the risk of DVT in acute stroke patients?

Aims:

- to find out if patients tolerate and are compliant when using the geko™ device.
- to ascertain the most suitable regimen for the geko™ device.

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Research Plan & Methodology

Explain how you intend to carry out the study. This includes the sampling strategy you intend to use, the data collection process and an analysis plan (750 words):

Sample size: 100 immobile adult stroke patients at risk of DVT. A formal calculation has not been carried out as there is no previous dataset on which to base the calculation.

Inclusion criteria:

- Not more than 24 hours between onset of stroke and hospital admission.
- Not able to get up from a chair/out of bed and walk to the toilets without the help of another person.

Exclusion criteria:

- Patients under 16 years of age.
- Patients who, in the opinion of the responsible clinician/nurse are unlikely to benefit from the geko™ device.
- Patients with a pacemaker.
- Patients with suspected deep vein thrombosis.
- Patients with hydrogel allergy.

Sampling strategy: Patients admitted to the hyperacute stroke ward at University Hospital of North Staffordshire will be approached to participate in the feasibility study.

Data collection: patients will be monitored at regular intervals whilst using the geko™ device and then followed-up at 90 days via a telephone interview.

Primary outcome: patient tolerability of geko™ device (via patient feedback questionnaire)

Secondary outcomes: modified Rankin Score (mRS) at 90 days (via follow-up phone interview)

DVT or PE suffered since discharge

patient compliance

Patient and Public Involvement: for the main RCT application a PPI focus group will need to be held to discuss the trial and any study documentation with a patient group.

Analysis plan: descriptive statistics will be presented for all outcomes. No further statistical analysis will be conducted as this is a feasibility study that will inform a larger RCT.

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Supervision Plan

Highlight the supervisory support available to the student (250 words):

The student will become a member of the Stroke Research in Stoke team. They will have regular supervision from the Stroke Research Manager (Dr T Nevatte) who will also help the student integrate into the stroke research team through attending research meetings, seminars and one-to-one sessions as needed. Clinical support will be provided by Professor Roffe and other clinical members of the research team as appropriate. The student will be exposed to all stages in the research process from idea conception and design through to trial delivery and results dissemination. We advocate a 'learning through practice' approach and expect the student to attempt all aspects of the study themselves including applying for approvals, designing study documentation, writing the study protocol, designing data capture forms, training ward staff where necessary, data coordination and dissemination. We actively promote our students to present their findings at national and international conferences and publish their results in peer-reviewed publications.

Any research-related training needs, for example conducting literature reviews, will be identified and delivered through attending training courses or targeted meetings with the supervisory team. The preparation of the student thesis will be overseen by Dr Nevatte and Professor Roffe.

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Signatures & Declarations

Please ensure that all signatures are collected – otherwise your application may be delayed:

Principal Investigator:	
Signature:	
Clinical Director :	
Signature:	

Deadline 31st September 2014

Please submit the electronic version of your intercalation project to Keira.Watts@uhns.nhs.uk. If you have any enquiries, feel free to contact the Academic Development Team by phone or e-mail: