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Clinical trial of electrical stimulation of leg muscles as a new way to prevent deep vein thrombosis and pulmonary embolism after stroke

Submission date
08/09/2022

Recruitment status
No longer recruiting

Registration date
23/09/2022

Overall study status
Completed

Last Edited
13/03/2026

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Venous thromboembolism (VTE) is a disabling and potentially fatal outcome that may be acquired in patients who are immobilised after an acute stroke. The standard treatment to prevent the development of VTE is to give anticoagulation medication. However, this is not recommended in the UK for patients who have had a stroke. Instead, the recommended treatment is intermittent pneumatic compression (IPC), where cuffs are placed around the lower legs and filled with air to help squeeze the legs and induce blood flow. However, not all patients are able to receive or tolerate IPC treatment. Another treatment which has shown promising results to prevent VTE in immobile patients after stroke is a medical device called the geko™ device. The geko™ device is a CE-marked medical device, which means the manufacturer has checked that the device complies with the essential safety and performance requirements for its intended use, which is to increase blood circulation to help prevent VTE. The aim of this study is to determine if the geko™ device is more effective at preventing VTE in immobile acute stroke patients, than the current IPC standard of care treatment.

Who can participate?
Immobile acute stroke patients aged 18 years or older

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). One group of participants will be treated with the geko™ device, a small, self-adhesive electrostimulation device, which stimulates a nerve in the lower leg that causes the calf muscles to contract. This will be applied for 24 hours daily, until the participant recovers mobility, is discharged, or for a maximum of 30 days. The other group of participants will receive the standard of care IPC treatment, until the participant recovers mobility, is discharged, or for a maximum of 30 days. Compression Doppler imaging, which is a special type of ultrasound imaging, will be carried out to assess the participants for deep vein thrombosis (DVT) any time there is a clinical suspicion of DVT, and in addition at 7 days after randomisation or at discharge

if earlier (optional compression Doppler) and/or 14 days after randomisation (mandatory visit). If indicated clinically, pulmonary embolism will be assessed by ventilation-perfusion scan or by computer tomography pulmonary angiogram (CTPA). Additional information including the NIH stroke score and adverse event information will be collected at 7 days (if practical) and 14 days after randomisation. At 14 days after randomisation, a device acceptability questionnaire and collection of other relevant information (e.g. final diagnosis, number of days in intensive care) will also be carried out. At 30 days after randomisation, information including incidences of symptomatic DVTs, PEs and antiplatelet/anticoagulation medication will be collected from medical notes. A final follow-up will be conducted 90 days after randomisation with the participant by phone (unless requested otherwise), to follow up on the participant's vital status, any DVT/PE diagnoses, as well as collecting information on the participant's health status and functional outcomes.

What are the possible benefits and risks of participating?
There are no guarantees that there are any direct benefits to the participant by participating in this study. However, the results of the study will help inform the recommended preventative treatment of venous thromboembolism for future immobile acute stroke patients, with the aim to improve recovery for patients. Participants will also contribute to the knowledge pool on the safety and performance of the geko™ device, which may also help improve treatment for future patients. There are no expected risks or disadvantages to participating in the study. Whichever group the participant is allocated to, their care will be overseen by their healthcare team. Some patients may develop a rash if they are allergic to the materials used in the study devices.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
February 2021 to November 2025

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof. Christine Roffe
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Contact information

Type(s)
Principal investigator

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Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05476913

Integrated Research Application System (IRAS)
315387

Protocol serial number
FSK-VTE-001

Study information

Scientific Title
A randomised controlled trial of the effectiveness of intermittent surface neuromuscular stimulation using the geko™ device compared with intermittent pneumatic compression to prevent venous thromboembolism in immobile acute stroke patients

Study objectives
The geko™ neuromuscular electrical stimulation (NMES) device is more effective than intermittent pneumatic compression (IPC) at preventing venous thromboembolism (VTE) events in patients with acute stroke.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/02/2023, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)208 104 8051; gmsouth.rec@hra.nhs.uk), ref: 23/NW/0001

Primary study design
Interventional

Study design
Prospective multicentre randomized controlled trial, single-blinded to the primary outcome

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of venous thromboembolism in acute stroke patients

Interventions
Current interventions as of 17/03/2025:
This study is looking at venous thromboembolism (VTE) prevention in patients suffering an acute stroke.
The Investigational arm will receive the geko™ device, a self-adhesive neuromuscular stimulator. This will be compared to the control arm using Intermittent Pneumatic Compression (IPC) as standard of care.
Participants will be allocated to a treatment group via an online randomisation tool, applied centrally across the study sites. After randomisation, the participant will immediately receive their allocated treatment for 24 hours daily, until they can walk again without help, are discharged into the community, for a maximum of 30 days or other criteria are met including e.g. primary outcome has been met (VTE condition) and treatment dose / full dose anticoagulation treatment administered.

Previous interventions:
This study is looking at venous thromboembolism (VTE) prevention in patients suffering an acute stroke.
The Investigational arm will receive the geko™ device, a self-adhesive neuromuscular stimulator. This will be compared to the control arm using Intermittent Pneumatic Compression (IPC) as standard of care.

Participants will be allocated to a treatment group via an online randomisation tool, applied centrally across the study sites. After randomisation, the participant will immediately receive their allocated treatment for 24 hours daily, until they can walk again without help, are discharged, or for a maximum of 30 days.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
geko™ device

Primary outcome(s)
Current primary outcome measure as of 17/05/2024:
Frequency of any symptomatic or asymptomatic Deep Vein Thrombosis (DVT) in the calf, popliteal or femoral veins or any Pulmonary Embolism (PE) within 30 days of randomisation. DVT will be diagnosed using compression Doppler imaging, conducted any time there is a clinical suspicion of DVT and at 7 days (optional) and 14 days (mandatory) after randomisation.

Previous primary outcome measure:
Frequency of any symptomatic or asymptomatic Deep Vein Thrombosis (DVT) in the calf, popliteal or femoral veins or any Pulmonary Embolism (PE) within 30 days of randomisation. DVT will be diagnosed using whole leg compression Doppler imaging, conducted any time there is a clinical suspicion of DVT and at 7 days and 14 days after randomisation, or at patient discharge if the patient recovers within a 3-day window of these follow-up timepoints.

Key secondary outcome(s)
Current secondary outcome measure as of 17/05/2024:
1. Patient tolerability to either study device assessed using the Device Acceptability Questionnaire at 14 days after randomisation.
2. Device effectiveness based on the frequency of patient death for any cause, confirmed fatal or non-fatal PE, any (symptomatic or asymptomatic) above knee DVT and a combination of these outcomes at 30 days after randomisation.
3. Device effectiveness based on the frequency of any symptomatic or asymptomatic DVT in popliteal or femoral veins and symptomatic calf vein DVT at 30 days after randomisation.
4. Leg pain level measured using a Numerical Rating Score (NRS) at 90 days after randomisation.
5. Health-related quality of life measured using EQ-5D-5L, at baseline if possible and at 90 days after randomisation.
6. Patient survival at 90 days after randomisation.
7. The frequency of venous thromboembolism (any symptomatic or asymptomatic DVT or PE) occurring between randomisation and 90 days after randomisation.
8. Device safety assessed by documenting adverse event assessments up to 30 days after randomisation or at patient discharge if earlier.
9. Stroke-related neurologic deficit assessed using the NIH stroke scale (NIHSS) at 7 days and 14 days after randomisation.

Previous secondary outcome measure:
1. Patient tolerability to either study device assessed using Device Acceptability Questionnaire at 30 days after randomisation or at patient discharge if earlier

2. Device effectiveness based on the frequency of patient death for any cause, confirmed fatal or non-fatal PE, any (symptomatic or asymptomatic) above knee DVT and a combination of these outcomes at 30 days after randomisation
3. Device effectiveness based on the frequency of any symptomatic or asymptomatic DVT in popliteal or femoral veins and symptomatic calf vein DVT at 30 days after randomisation
4. Leg pain level measured using a Numerical Rating Score (NRS) at 90 days after randomisation
5. Health-related quality of life measured using EQ-5D-5L, at baseline if possible and at 90 days after randomisation
6. Patient survival at 90 days after randomisation
7. The frequency of venous thromboembolism (any symptomatic or asymptomatic DVT or PE) occurring between randomisation and 90 days after randomisation
8. Device safety assessed by documenting adverse event assessments at 30 days after randomisation or at patient discharge if earlier
9. Stroke-related neurologic deficit assessed using the NIH stroke scale (NIHSS) at 7 days, 14 days and 30 days after randomisation or at patient discharge if the patient recovers earlier

Completion date
30/11/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/08/2025:
1. Aged 18 years or older
2. Clinical diagnosis of acute stroke (WHO criteria)
3. Within 72 hours of symptom onset
4. Not able to get up from a chair/out of bed and walk to the toilet without the help of another person

Previous inclusion criteria:
1. Aged 18 years or older
2. Clinical diagnosis of acute stroke (WHO criteria)
3. Within 36 hours of symptom onset
4. Not able to get up from a chair/out of bed and walk to the toilet without the help of another person

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
230

Key exclusion criteria
1. Inability to gain consent from the patient, or a declaration from a Personal Consultee or Nominated Consultee
2. Unwitnessed onset with a long lie on the floor before admission
3. Clinically apparent deep vein thrombosis at screening
4. Patient is expected to require palliative care within 14 days
5. Patient does not live in the local catchment area and is expected to be transferred to their local hospital for ongoing care
6. Patient has recently been involved in or is currently involved in a clinical trial for either a medical device or medicinal product, within the past 3 months, with the exception: if co-enrolment is not considered to impact adverse events or outcomes in the opinion of the Chief Investigator
7. Contraindications for the use of the geko™ device:
7.1. Allergy to hydrogel constituents
8. Contraindications to IPC:
8.1. Severe peripheral vascular disease
8.2. Large leg ulcers requiring extensive bandaging (small ulcers or skin breaks with flat coverings are not an exclusion)
8.3. Severe oedema
8.4. Leg deformities making appropriate fitting impossible
9. Uncontrolled congestive cardiac failure
10. Pregnancy or breastfeeding
11. Single or double leg amputations

Date of first enrolment
06/07/2023

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
England
BA1 3NG

Study participating centre
Whiston Hospital
St. Helens & Knowsley Hospital
Warrington Road
Prescot
England
L35 5DR

Study participating centre
Fairfield General Hospital
Fairfield General Hospital
Rochdale Old Road
Bury
England
BL9 7TD

Study participating centre
West Suffolk Hospital
Hardwick Ln
Bury Saint Edmunds
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IP29 5DN

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
England
CH2 1UL

Study participating centre
Royal Bournemouth General Hospital
Castle Lane East
Bournemouth
England
BH7 7DW

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
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CB2 0QQ

Study participating centre
Queens Medical Centre
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England
NG7 2UH

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
England
HA1 3UJ

Study participating centre
Milton Keynes University Hospital
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MK6 5LD

Study participating centre
New Cross Hospital
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Heath Town
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WV10 0QP

Study participating centre
Salford Royal Hospital
Stott Lane
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M6 8HD

Study participating centre
Yeovil District Hospital
Higher Kingston
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BA21 4AT

Study participating centre
Stepping Hill Hospital
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SK2 7JE

Study participating centre
Kings College Hospital
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Queen Elizabeth Hospital
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Study participating centre
Kent and Canterbury Hospitals NHS Trust
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CT1 3NG

Sponsor information

Organisation
Firstkind Limited

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The pseudo-anonymised study dataset generated during and/or analysed during the current study will be stored in a non-publicly available database (electronic data capture system). The database will be hosted by Medrio electronic data capture (EDC). This study dataset will be

shared with Dr Martyn Lewis from the Clinical Trials Unit at Keele University, for analysis and generation of data summaries. This data may also be analysed and summarised by the study Sponsor, Firstkind Ltd. The (de-identified) compression Doppler images will be stored in an encrypted, external hard drive provided by the Sponsor for study purposes. These will then be transferred to a secure server in the UK. 5% of the compression Doppler images will be analysed by an independent sonographer for quality assurance purposes. Patients will be informed via the study Patient Information Sheet regarding the sharing of these de-identified datasets with the Sponsor and with the independent qualified experts.

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Christine Roffe (christine.roffe@uhnm.nhs.uk) after publication.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5.0	28/03/2025	13/03/2026	No	No
Statistical Analysis Plan	version 1.1	15/12/2025	16/12/2025	No	No