1. TRIAL SUMMARY

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| Trial 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 | |
| Internal ref. no. (or short title) | GEKO Venous Thromboembolism Prevention Study | |
| Trial Design | Prospective, multicentre, randomised controlled trial | |
| Trial Participants | Age 18 years or older  Clinical diagnosis of acute stroke (WHO criteria)  Within 36 hours of symptom onset  Not able to get up from a chair/out of bed and walk to the toilet without the help of another person | |
| Planned Sample Size | At least 1200 | |
| Treatment duration | 30 days or until the patient is independently mobile or discharged into the community, whichever is the earliest | |
| Follow up duration | 3 months | |
| Planned Trial Period | 01Dec 2022-30 Nov 2025 | |
| Inclusion/Exclusion Criteria | Inclusion Criteria:   1. Age 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 | 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 on-going 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. (A live document containing a list of approved studies will be included in a reference document made available to all study sites and available upon request) 7. Contraindications for the use of the geko™ device:    * Allergy to hydrogel constituents. 8. Contraindications to IPC:    * Severe peripheral vascular disease    * Large leg ulcers requiring extensive bandaging (small ulcers or skin breaks with flat coverings are not an exclusion)    * Severe oedema.    * Leg deformities making appropriate fitting impossible 9. Uncontrolled congestive cardiac failure 10. Pregnancy 11. Single or double leg amputations |
| Objectives | | Outcome Measures |
| Primary | To determine whether the geko™ device is more effective at preventing venous thromboembolism within 30 days of randomisation than intermittent pneumatic compression in immobile patients with acute stroke. | Any symptomatic or asymptomatic deep vein thrombosis (DVT) in the calf, popliteal or femoral veins or any confirmed fatal or non-fatal pulmonary embolism (PE) within 30 days of randomisation |
| 1.Secondary outcomes up to 30 days | To compare effectiveness and tolerability | 1. Patient tolerance of the device at day 14 2. Adherence to allocated treatment to day 30 3. Death from any cause by day 30 4. Confirmed fatal or non-fatal PE to day 30 5. Any symptomatic or asymptomatic above knee DVT to day 30 6. Any symptomatic or asymptomatic DVT in popliteal or femoral veins and symptomatic calf vein DVT to day 30 7. Combined c-e |
| 2. Secondary outcomes at 90 days | To compare survival, functional outcomes, and quality of life | 1. Leg pain (NRS scale) 2. Death from any cause 3. Any symptomatic or asymptomatic DVT or PE occurring between randomisation and final follow-up 4. Combined b and c 5. Disability (modified Rankin Scale) 6. Health related quality of life (EQ-5D-5L) 7. Place of residence. |
| Exploratory and health economic outcomes | To compare exploratory and health economic outcomes | 1. Early neurological recovery (difference in NIHSS between baseline and 7 days) 2. Neurological recovery (difference in NIHSS between baseline and 14 days) 3. Stroke recurrence up to 30 d 4. Length of hospital stay at 90 days 5. Home time at 90 d |
| Safety outcomes up to 30 days | To assess safety | 1. Falls with significant injuries 2. Fractures 3. Skin breaks 4. Adverse events (additional to those listed above) |
| Investigational Device | The geko™ neuromuscular electrostimulation device (Firstkind Ltd, High Wycombe, UK) | |
| Control | Intermittent pneumatic compression (IPC) using any NHS approved device | |
| Application of the device/control | geko™ therapy / IPC will be applied to both legs as soon as possible after randomisation and continued 24 hours a day until independent mobilisation/discharge into community or for a maximum of 30 days. | |
| Funding | National Institute for Health Research i4i Research Grant | |

1. A diagram of a company

   Description automatically generated TRIAL FLOW CHART