

STATISTICAL ANALYSIS PLAN (SAP)

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 (GEKO Venous Thromboembolism Prevention Study)

This statistical analysis plan was designed taking into account the guidelines for the content of statistical analysis plans in clinical trials.¹

If there is a difference in the analysis plan given in the protocol and the analysis plan specified in the SAP, the SAP will take preference.

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Declaration regarding undertaking of the analysis

Muhammad Usman (study statistician) will be undertaking data cleaning and analysis of the study data under the guidance and supervision of Martyn Lewis (senior statistician / Professor of Biostatistics). Analysis of the primary clinical endpoint and key secondary outcome(s) will be performed independently by the senior statistician to ensure the integrity of the main findings of the study.

With reference to Protocol version: 5.0 (Date: 28/03/2025)

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Version History Log

This section should detail the key elements of the changes to the successive versions. Minor changes should be labelled as, for example, version 2.0 to 2.1. Major changes should instead be labelled as version 2.0 to 3.0.

Version	Date implemented	Section no. changed	Details of changes with justification
1.0	10/Dec/2025	N/A	N/A - First version
1.1	15/Dec/2025	Study team (pg 2); Declaration regarding undertaking of the analysis (pg 3)	Correction to Muhammad Usman's name.

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Glossary of terms / Abbreviations

AE: Adverse Event

CI: Chief Investigator

CTPA: Computer Tomography Pulmonary Angiogram

DMC: Data Monitoring Committee

DVT: Deep Vein Thrombosis

EDC: Electronic Data Capture

EQ-5D-5L: EuroQOL quality of life assessment tool

HR: Hazard Ratio

IFU: Instructions for Use

ITT: Intention To Treat

IPC: Intermittent Pneumatic Compression

ISRCTN: International Standard Randomised Controlled Trials Number

IQR: Inter Quartile Range

mRS: Modified Rankin Scale

NIHSS: National Institutes for Health Stroke Scale

NMES: Neuromuscular Electrostimulation

NRS: Numerical Rating Scale

PE: Pulmonary Embolism

PI: Principal Investigator

QC: Quality Control

SADE: Serious Adverse Device Effect

SAE: Serious Adverse Event

TSC: Trial Steering Committee

VTE: Venous Thromboembolism

1. Background and Aims

1.1 Background

Venous thromboembolism (VTE) is a major health issue worldwide causing preventable death and long-term disability due to chronic leg swelling, pain, and skin changes (post-thrombotic syndrome). The Global Burden of Disease Study reports an incidence of 115-269/100,000 (0.1-0.3%) and a mortality of 9.4-32.3/100,000 (0.01- 0.03%) for venous thromboembolism, only slightly lower than the mortality rate for stroke.² The risk of VTE has been reported to be considerably higher in medical hospital inpatients (5.5%), even with VTE prophylaxis (in 53%).³ VTE is associated with a high incidence of long-term disability and doubles the risk of permanent work-related disability.⁴ This is mainly due to post-thrombotic syndrome, which has been reported to occur on 50% of cases.^{5 6 7}

Stroke patients are at particular risk of VTE due to immobilisation and limb paralysis. VTE incidence varies between published studies, depending on the population studied and the method of diagnosis.^{8 9 10 11 12 13} In 2009, the Clots in Legs Or sTockings after Stroke (CLOTS) 1 trial reported an incidence of 10% for deep vein thrombosis (DVT) diagnosed by Doppler, of which 7% were asymptomatic and 3% were symptomatic, and there was a 1% incidence of symptomatic PE¹⁴. In the CLOTS-3 study published in 2013 VTE in the control group was higher with 21% DVT (symptomatic or asymptomatic) and 2% symptomatic PE.¹⁵ The risk of VTE is greatest in the first month after stroke (Hazard ratio (HR) 19.7) and declines to 10.6 between 30 and 90 days after the stroke, with roughly similar risks for DVT (HR 19.1) and pulmonary embolism (HR 20.2).¹⁶ Prevention of VTE is therefore important. However, the options for VTE prevention are limited. Prophylactic anticoagulation is almost universally used for VTE prevention, but has no overall benefit in patients with stroke, because of the increased bleeding risk, with the impact of reductions in pulmonary embolism being negated by a matched increase in significant intracranial bleeds.¹⁷ Graduated compression stockings, key aspects of thromboprophylaxis in medical and surgical hospital inpatients, do not prevent VTE in patients with acute stroke.¹⁴ Intermittent pneumatic compression (IPC) has robust evidence of effectiveness and safety in stroke patients¹⁵ and is the treatment of choice,

endorsed by major national and international guidelines.^{18 19 20} It is standard of care in the UK.¹³ However, about 30% of patients have contraindications or are unable to tolerate IPC.¹⁵ Neuromuscular electrical stimulation (NMES) prevents venous stasis by stimulation of muscle contractions in the lower leg and might be an alternative method of VTE prevention. A meta-analysis of studies using neuromuscular stimulation including 904 surgical and spinal injury patients suggested that NMES is better than no VTE prophylaxis, but no more effective than standard methods of VTE prevention.²¹ A larger more recent meta-analysis including 1685 surgical patients confirmed these findings, but only included small studies with high risk of bias and concluded that more evidence from high quality RCTs was needed.²²

The geko™ (Firstkind Ltd, High Wycombe, UK) is a small, self-adhesive, disposable, battery powered NMES device which induces contraction of calf muscles via stimulation of the peroneal nerve. There is evidence from studies in healthy volunteers that it is effective in increasing venous blood flow in healthy volunteers²³ and in patients with chronic venous stasis.²⁴ Use of the geko™ is approved by the National Institute for Care and Excellence (NICE) for patients at high risk of VTE who have contraindications to other forms of mechanical or pharmacological VTE prophylaxis.²⁵ There are three small RCTs of NMES via the peroneal nerve compared to no mechanical or pharmacological prevention^{26 27 28} with 6/111 (5.4%) DVT in the active and 20/111 (18%) in the control group ($p=0.003$). Three further studies^{29 30 31} compare NMES of the peroneal nerve against IPC or GCS with DVT in 0/88 in the active and 3/98 (3.1%) in the control group ($p=0.2$). There is no evidence from RCTs to establish effectiveness of NMES of the peroneal nerve in patients with acute stroke.

IPC is an effective means of VTE prevention in stroke patients. However, it is not well tolerated, with a contraindications or intolerance of the device in a third of patients. NMES via the peroneal nerve improves venous blood flow in the lower leg. Emerging evidence from small studies in surgical patients suggests that it may be effective in VTE prevention.

2. Aim

The aim of this trial is to compare the effectiveness of NMES of the peroneal nerve via the geko™ device with IPC for the prevention of VTE in immobile patients after acute stroke.

Primary objective

To determine whether the geko™ device is more effective at preventing VTE (any symptomatic or asymptomatic DVT in the calf, popliteal or femoral veins or any PE) within 30 days of randomisation when compared to IPC (standard of care) in immobile patients with acute stroke.

Secondary objectives

- To compare effectiveness and tolerability
- To compare the survival, functional outcomes, and quality of life
- To compare exploratory and health economic outcomes
- To compare safety outcomes

3. Design

3.1 Trial design and setting

This is a prospective, multicentre, randomised controlled trial single blinded to the primary outcome, designed to determine whether the geko™ device is more effective at preventing VTE (any symptomatic or asymptomatic DVT in the calf, popliteal or femoral veins or any pulmonary embolism (PE)) within 30 days of randomisation when compared to standard of care (IPC) in immobile patients with acute stroke. There are two arms in the trial consisting of: no intervention group i.e. IPC (standard of care) and intervention group i.e. geko™ T-3 or variant (24 hours daily therapy).

The trial will be run in the emergency departments and on the acute stroke unit of primary and comprehensive stroke centres in the UK. Patient identification will follow the clinical pathway with patients arriving via the emergency department, where hyper acute stroke treatments such as thrombolysis, reversal of anticoagulation, and blood pressure management are initiated, and decisions about mechanical thrombectomy are made. After initial hyper acute stroke treatments are given, patients are admitted to the acute stroke

unit, where they continue to be cared for until discharge or transfer to a rehabilitation unit. Patient enrolment will take place in the emergency department or on the acute stroke unit, after acute treatments have been given and while waiting for, or after, mechanical thrombectomy, if this is clinically indicated. Participating sites will include the University Hospital of North Midlands NHS Trust and other acute stroke services who meet qualifying criteria.

3.2 Trial randomisation and blinding

Participants are randomly assigned to treatment groups, with 1:1 ratio to receive either geko™ or IPC. The assignment is determined by 1:1 randomisation, with three stratification variables [study site, National Institutes for Health Stroke Scale (NIHSS),³² stroke type] and random permuted blocks. Specifically, the allocation sequence allows for at least 120 strata: 20 or more recruitment sites; three NIHSS categories (0-6, 7-15, >15), and two stroke types (ischemic, haemorrhagic). The allocation schedule for group assignment is created by a qualified statistician (MA Lewis) from Keele University. This allocation schedule is uploaded into the trial specific electronic data capture (EDC) system Medrio, which allows allocation to be administered centrally across the sites. This central remote randomisation service is utilised to ensure allocation concealment from the recruiting study sites.

Randomisation is implemented by a member of the research team and the allocated treatment is prescribed immediately. The EDC system directly informs the local principal investigator (PI) and/or the lead research nurse of each randomisation. Participants and research staff involved in the collection of inpatient data, and the clinical teams are aware of the treatment allocation, as the devices used for the intervention and control look, feel and sound very different. The trial is single blinded for the primary outcome assessment based on the compression Dopplers at Day-7 (optional) and Day-14 (mandatory). Devices are taken off before participants have their compression Doppler procedure to blind the sonographer to the allocated treatment. Where possible single blinding is maintained. However, for patients who have an emergency clinical investigation for DVT or PE, it may not be possible to blind the assessor (i.e. sonographer or radiographer) conducting the assessment due to the urgency of the procedure. Data on symptomatic VTE incidence is

taken from information available on hospital information systems. The trial will be fully unblinded after the database lock, completion of the analysis plan and publication of the trial protocol.

4. Study and evaluative population

4.1 Eligibility criteria

The following is participants inclusion criteria into the trial.

- Age 18 years or older
- Clinical diagnosis of acute stroke (WHO criteria)
- Within 72 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

The following is participants exclusion criteria into the trial.

- Inability to gain consent from the patient, or a declaration from a personal consultee or nominated consultee
- Unwitnessed onset with a long lie on the floor before admission
- Clinically apparent DVT at screening
- Patient is expected to require palliative care within 14 days
- Patient does not live in the local catchment area and is expected to be transferred to their local hospital for on-going care.
- 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 CI.
- Contraindications for the use of the geko™ device³³
 - Allergy to hydrogel constituents
- Contraindications to IPC¹⁵
 - 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
- Uncontrolled congestive cardiac failure
- Pregnancy
- Single or double leg amputations

4.2 Consent and enrolment

Informed consent or declaration is obtained for each participant before they undergo any interventions related to the trial. The participant/personal consultee/nominated consultee received a copy of the signed and dated forms. If there is any subsequent amendment to the final protocol or if new information becomes apparent, which might affect a participant's participation in the trial, continuing consent is obtained using an amended consent form which is signed by the participant. If the participant does not have capacity, the personal consultee/nominated consultee is informed and an amended personal consultee declaration form or amended nominated consultee declaration form, is signed by the respective parties. Patient consent is the point of enrolment into the trial. Once enrolled, the patient is assigned a trial ID code.

4.3 Participant identification and recruitment

Adult patients admitted to hospital with an acute stroke are to be recruited. There is no upper age limit and no exclusion of patients on the grounds of frailty, dependency, sex, race, or religion.

As soon as possible after hospital arrival, the research team, or the emergency department screen and approach the patient or their relative/friend. Hyperacute stroke treatments such as thrombolysis or thrombectomy for ischemic strokes or blood pressure management patients with intracerebral haemorrhage is not delayed for trial inclusion. For patients with wake-up stroke the time of onset is defined by the time they wake up with symptoms. The investigator or their nominee, e.g. from the research team or a member of the participant's usual care team, inform the participant, their legal representative, or an independent physician is informed of all aspects pertaining to participation in the trial. It is explained to the potential participant that entry into the trial is entirely voluntary and that their

treatment and care is not affected by their decision. Screening is based on clinical history and exam of the patient. No blood tests, scans, or other investigations are required.

5. Outcomes

5.1 Primary outcome

The primary outcome is designed to determine effectiveness for prevention of VTE, and it is any symptomatic or asymptomatic DVT in the calf, popliteal or femoral veins or any PE within 30 days of randomisation (yes or no).

The timepoint of evaluation of primary outcome measure is within 30 days of randomisation using leg Dopplers at 7 days where practical, and at 14 days (mandatory) for asymptomatic DVTs, plus imaging for PE when clinically indicated and leg Dopplers when clinically indicated. PE is assessed by ventilation perfusion scan or by computer tomography pulmonary angiogram (CTPA), as indicated clinically. Other forms of imaging, diagnosis methods and post-mortem results will also be accepted to confirm a clinically indicated PE or DVT diagnosis.

5.2 Secondary outcomes

Secondary outcomes are assessed at 14 days, 30 days and at 90 days, when most of the patients are expected to have returned back to their primary residence. At day-14, the effectiveness and tolerability of the devices is collected. The 90-day outcomes assess longer term effects on survival, functional recovery, and quality of life. The list of outcomes that measured the effectiveness and tolerability and the effect on survival, functional outcomes, and quality of life is as following.

To compare effectiveness and tolerability

- a. Patient tolerance of the device (At 14 days after randomisation)
- b. Adherence to allocated treatment (At 30 days after randomisation)
- c. Death from any cause (At 30 days after randomisation)
- d. Confirmed fatal or non-fatal PE (At 30 days after randomisation)
- e. Any (symptomatic or asymptomatic) above knee DVT (At 30 days after randomisation)

- f. Any (symptomatic or asymptomatic) DVT in popliteal or femoral veins and symptomatic calf vein DVT (At 30 days after randomisation)
- g. Combined c-e

To compare the effect on survival, functional outcomes, and quality of life (At 90 days after randomisation)

- h. Leg pain via numerical rating scale (NRS) ³⁴
- i. Death from any cause
- j. Any symptomatic or asymptomatic DVT or PE occurring between randomisation and final follow-up
- k. Combined b and c
- l. Disability [modified Rankin Scale (mRS)] ^{35 36}
- m. Health related quality of life (EQ-5D-5L) ³⁷
- n. Place of residence after discharge

5.3 Exploratory and health economic outcomes

Exploratory outcomes are collected to ascertain differences in stroke severity and recovery. They are important in understanding potential differences in the primary outcome (stroke severity) and the effect on costs and the NHS (length of stay, home time i.e. when patient was discharged into the community). The following is the list of exploratory outcomes.

- To compare the effect of exploratory and health economic outcomes
 - a. Early neurological recovery (NIHSS³² day 7 – NIHSS at baseline)
 - b. Neurological recovery (NIHSS day 14 – NIHSS at baseline)
 - c. Stroke recurrence (new infarct or bleed on imaging or NIHSS increase of 8 points or more without confirmation by imaging) (At 30 days after randomisation)
 - d. Length of hospital stay until discharge into the community (At 90 days after randomisation)
 - e. Home time ^{38 39 40 41} (At 90 days after randomisation)
 - f. Quality of life in relation to venous problems (VEINES-QOL)^{42 43 44}

5.4 Safety outcomes

These include known adverse effects of both IPC and geko™ therapy (discomfort, skin irritation), potential adverse events (e.g. falls with significant injuries and fractures due to the effect of the devices on mobility) and other non-specified adverse events. The following is the list of safety outcomes.

- To compare safety (Up to 30 days after randomisation or discharge, whichever comes earlier)
 - a. Falls with significant injuries
 - b. Fractures
 - c. Skin breaks
 - d. Adverse events (additional to those listed above)

6. Sample size / Power

The trial size is based on the hypothesis that the geko™ device is more effective than IPC at preventing VTE events. This is supported by the results of our local audit, where VTE halved after we introduced the geko™ device as an additional option for VTE prevention, and data from studies with healthy individuals, which show that the geko™ device is more effective at improving arterial and venous blood flow in the lower limbs. The incidence of symptomatic or asymptomatic VTE in stroke patients treated with IPC is 17.2% at 30 days. A 40% reduction of VTE can be demonstrated with 90% power and an alpha of 0.05, assuming a 5% loss to follow-up with a trial size of 1200 patients, 600 per arm.

As a result of early stopping of the trial we will undertake a post-hoc power calculation with alpha set as 0.05 (evidence) and 0.2 (signal) for an effect in the study.

7. Baseline demographic and clinical characteristics

Baseline data is collected before randomisation. Some baseline data may be taken from source data obtained during patient admittance, which may occur prior to obtaining

participant consent/consultee advice. A mismatch in dates for this reason, will not constitute a protocol deviation.

Baseline clinical data

- Type of consent [patient/personal consultee/nominated consultee]
- Date and time of symptom onset
- Date and time of admission
- Age
- Sex
- Previous DVT (and number of times this occurred)
- Previous PE (and number times this occurred)
- Known diabetes
- Known myocardial infarction in the past
- mRS pre-Stroke
- EQ-5D pre-stroke
- Place of residence
- On antiplatelets (yes/no); if yes: aspirin, clopidogrel, dipyridamole, ticagrelor, other antiplatelet agent (specify)
- On prophylactic dose anticoagulant (yes/no); if yes: unfractionated heparin, dalteparin, enoxaparin, other (specify)
- On full dose anticoagulant (yes/no); if yes: warfarin, apixaban, edoxaban, rivaroxaban, dabigatran, other direct acting anticoagulant, dalteparin, enoxaparin, other low molecular weight heparin, unfractionated heparin
- On diuretics (yes/no)
- Covid-19 infection within the last 30 days (yes/no/unknown)
- Covid-19 vaccination within the last 30 days (yes/no)
- Blood pressure
- Heart rate
- Temperature
- Oxygen saturation
- Stroke pathology (cerebral infarct/ intracerebral haemorrhage)

- NIHSS
- Leg swelling yes/no; if yes (one or both/ pitting or non-pitting)
- Post-thrombotic syndrome (skin discoloration/sclerosis with change of leg shape/current or past leg ulceration)
- Thrombolysed (yes/no)
- Mechanical thrombectomy (yes/no)
- Treatment with tranexamic acid for haemorrhages (yes/no)
- Treatment with other haemostatic agents (yes/no); if yes: octaplex, FVII, platelets, vitamin K, other [specify]
- Indicate option whether the participant will undertake the Day 7 compression Doppler if it is considered practical.

Appropriate descriptive statistics (mean, standard deviation, median, lower and upper quartiles, minimum, maximum or frequencies and percentages) for the demographic and clinical outcome measures at baseline, will be used to assess balance between the randomised arms at baseline, but no formal statistical comparisons will be performed. Baseline characteristics will also be descriptively compared between those randomised and those analysed for the primary outcome (if there is greater than 10% loss in primary outcome data) to see if the attrition has introduced any imbalances. Flow of patients will be illustrated in a CONSORT flow diagram (as shown in Figure 1).

8. Methods of analysis

8.1 Primary outcome analysis

VTE is recorded as yes or no for each patient at 30 days and will be compared between the two groups. The primary analysis will be intention to treat (ITT) (analysed according to randomised allocation, regardless of duration of interventional treatment). The primary analysis will be by a logistic mixed regression model, adjusted for treatment site (random factor), NIHSS category ($\text{NIHSS} \leq 6, 7-15, >15$) and stroke type (fixed factors), and reported as odds ratio estimates with 80% and 95% confidence intervals and p-values. An NNT (Number-Needed-to-Treat) along with 80% and 95% confidence intervals will be calculated using the

derived odds ratio from the primary calculation and the probability of the event in the control group. Sensitivity analyses will include a per protocol population (any participants randomised and who have had at least 50% of the allocated treatment i.e. more than 15 days treatment or more than 50% of days treatment before discharge home) and a dataset with imputed data for the primary outcome, where there is substantive and imbalanced missing data (using best-/worst- case scenarios - if there is >10% missing data for the primary measure and there is >5% difference in attrition rate between trial arms (otherwise risk of bias will be low)) .

8.2 Secondary outcome analysis

Between-group comparison of secondary outcomes (section 4.2) will be based on an appropriate mixed regression model for the outcome (linear for continuous, generalised linear for categorical, and Cox proportional hazards for time-to-event), adjusted for treatment site (random factor), NIHSS category, stroke type and the corresponding baseline value as appropriate (fixed factors).

8.3 Sub-group analyses

Sub-group analyses will include stroke aetiology (infarct/haemorrhage), stroke severity (NIHSS≤6,7-15,>15), concomitant treatments (thrombolysis/no thrombolysis, anticoagulation/no anticoagulation, thrombectomy/no thrombectomy), and infection with Covid-19 (yes/no). Focus will be on the primary outcome variable only (as per detail in 7.2 above) but additionally modelling the interaction term of the subgroup variable (in separate analyses for each subgroup) with the treatment group variable. The nature of this analysis is exploratory as it was not formally powered.

8.4 Sensitivity analysis

In a sensitivity analysis, the primary analysis will repeat by additionally adjusting for any variables with marked imbalance at baseline and for other post randomisation factors which are expected to affect outcome, e.g. thrombolysis (yes/no), mechanical thrombectomy, anticoagulation (none/ 7 days or less/ more than 7 days) or Covid-19 (yes/no). Best/worst

case scenario imputation will be carried out if there is imbalanced follow up data (as detailed in s7.2 above).

8.5 Interim analysis

No interim analysis is planned.

8.6 Procedures to account for missing or spurious data

Missing data will be described, for example, by presenting the number and percentage of individuals in the missing category in total and split by study arm. The day 7 compression Doppler was originally outlined to be mandatory, but due to resource limitations to support this study requirement, the study design was amended so that the day 7 compression doppler became optional (as per Protocol V3.0, dated 14 Nov 2023), therefore missing data for this item will only be recorded as 'missing' if the investigator had opted into performing both day 7 and day 14 compression Dopplers. The NIHSS at day 7 will only be done if practical i.e. the participant is still in hospital at that time point. All data collected on data collection forms will be used, since only essential data items will be collected. No data will be considered spurious in the analysis since all data will be checked and cleaned before analysis.

8.7 Adverse event data

Data related to adverse event will be reported for each intervention arm and in total.

9. References

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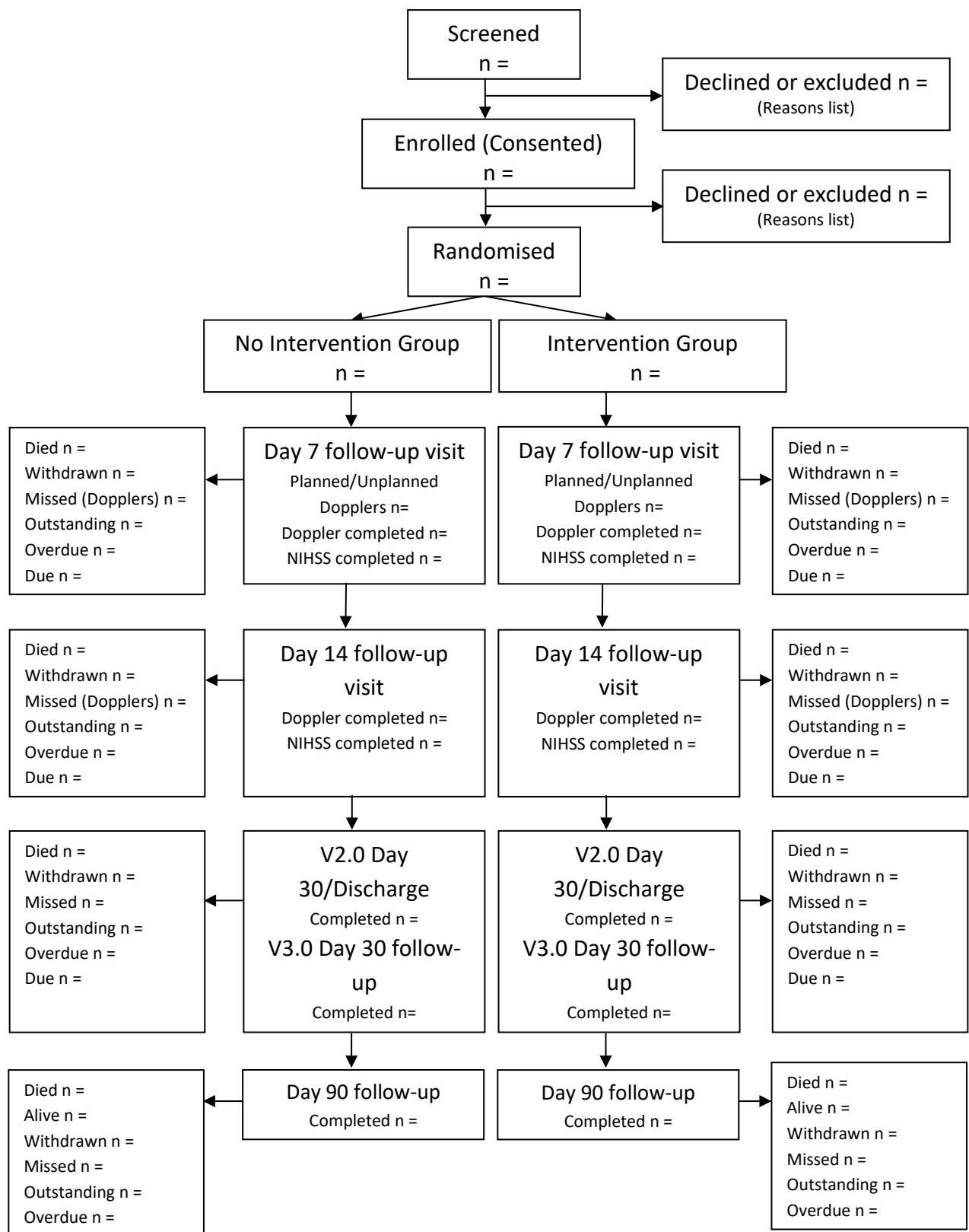


Table 1. Consent breakdown*

Consent	No Intervention Group	Intervention Group	All patients
Consent			
Fully informed written consent given from patient			
Written consent given from a Consultee			
Personal Consultee			
Nominated Consultee			

*An additional 3 participants were consented but subsequently determined to be screen failures and withdrawn prior to randomisation.

Table 2. Clinical characteristics at Screening / Baseline / Randomisation

Randomisation		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of patients randomised	N						
Onset to randomisation [hh:mm] Baseline Medical History and Concomitant Medication Status MHSYMDAT, MHSYMTIM Subtract Date and Time from RAND Form: Randomisat_CREATE_DTM (Timestamp)	Mean (SD) / Median (IQR) {range}						
Age, years "DM" form	Mean (SD) / Median (IQR) {range}						
Sex, male "DM" form	N (%)						
Sex, female "DM" form	N (%)						
Sex, unknown "DM" form	N (%)						
Sex, undifferentiated "DM" form	N (%)						
Stroke pathology Baseline Medical History and Concomitant Medication Status							
Cerebral infarct* COUNT OF MHSP = Cerebral infarct	N (%)						
Intracerebral haemorrhage* COUNT OF MHSP = Intracerebral haemorrhage	N (%)						
Relevant Medical history [yes]	N (%)						
No of relevant medical history events reported	Mean (SD) / Median (IQR) {range}						
Previous VTE incidences and other comorbidities: Baseline Medical History and Concomitant Medication Status							

Randomisation		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
DVT COUNT OF MHDVTYN = Yes	N (%)						
PE COUNT OF MHPEYN = Yes	N (%)						
Diabetes mellitus COUNT OF MHDBYN = Yes	N (%)						
Past myocardial infarction COUNT OF MHMIYN = Yes	N (%)						
Leg swelling – Right Leg COUNT OF MHLS = Right Leg	N (%)						
Leg swelling with pitting - Right Leg COUNT OF MHLS = Right Leg AND MHLSSP = Pitting	N (%)						
Leg swelling – Left Leg COUNT OF MHLS = Left Leg	N (%)						
Leg swelling with pitting - Left Leg COUNT OF MHLS = Left Leg AND MHLSSP = Pitting	N (%)						
Leg swelling – Both Legs COUNT OF MHLS = Both Legs	N (%)						
Leg swelling with pitting - Both Legs COUNT OF MHLS = Both Legs AND MHLSSP = Pitting	N (%)						
Leg swelling – none COUNT OF MHLS = Neither - No swelling	N (%)						
Post-thrombotic syndrome COUNT OF MHPTS= Yes	N (%)						
Post-thrombotic syndrome – with skin discoloration COUNT OF MHPTS= Yes AND MHPTSSP = skin discoloration	N (%)						
Post-thrombotic syndrome – with sclerosis with change of leg shape COUNT OF MHPTS= Yes AND MHPTSSP = sclerosis with change of leg shape	N (%)						
Post-thrombotic syndrome – current or past leg ulceration COUNT OF MHPTS= Yes AND MHPTSSP = current or past leg ulceration	N (%)						
Baseline treatments Baseline Medical History and Concomitant Medication Status							
Other mechanical prophylaxis since admission COUNT OF MH_MECH_PROPHYLAXIS = Yes	N (%)						
Thrombolysis COUNT OF MHTHMBYN = Yes	N (%)						
Mechanical Thrombectomy COUNT OF MHMT = Yes	N (%)						

Randomisation		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Tranexamic acid for haemorrhages COUNT OF MH_TRANEXAMIC_ACID = Yes	N (%)						
Other haemostatic agents COUNT OF MH_HAEMOSTATIC_AGENTS = Yes	N (%)						
Octaplex COUNT OF MH_HAEMOSTATIC_SPECIFY = Octaplex	N (%)						
FVII COUNT OF MH_HAEMOSTATIC_SPECIFY = FVII	N (%)						
Platelets COUNT OF MH_HAEMOSTATIC_SPECIFY = Platelets	N (%)						
Vitamin K COUNT OF MH_HAEMOSTATIC_SPECIFY = Vitamin K	N (%)						
Other COUNT OF MH_HAEMOSTATIC_SPECIFY = Other	N (%)						
Concomitant Medications							
Baseline Medical History and Concomitant Medication Status							
Antiplatelet medication COUNT OF MHCMA = Yes	N (%)						
Prophylactic dose anticoagulant COUNT OF MHCMPAC = Yes	N (%)						
Full dose anticoagulant COUNT OF MHCM_FD_ANTICOAGULANTS = Yes	N (%)						
Diuretic medication MCHCDU = Yes	N (%)						
Place of residence prior to admission:							
Baseline Medical History and Concomitant Medication Status							
Private residence COUNT OF MHLOC = Private residence	N (%)						
Care home COUNT OF MHLOC = Care home	N (%)						
Hospital COUNT OF MHLOC = Hospital	N (%)						
Other institution COUNT OF MHLOC = Other	N (%)						
Covid-19:							
Covid-19 Status							
COVID-19 status collected = Yes CVPERFYN = Yes	N (%)						
Subject had COVID-19 in last 30 days CV19YN = Yes	N (%)						
Subject had COVID-19 vaccination within last 30 days CVAXYN = Yes	N (%)						
Vital signs:							
Vital Signs							
Systolic Blood pressure (mmHg) AVERAGE OF: VSSYSBP	Mean (SD) / Median (IQR)						
Diastolic Blood Pressure (mmHg) AVERAGE OF Vital Signs: VSDIABP	Mean (SD) / Median (IQR)						

Randomisation		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Heart rate, (beats/minute) AVERAGE OF Vital Signs: VSHR	Mean (SD) / Median (IQR)						
Body temperature, Celsius AVERAGE OF Vital Signs: VSTEMP	Mean (SD) / Median (IQR)						
Oxygen saturation (%) AVERAGE OF Vital Signs: VSOXYSAT	Mean (SD) / Median (IQR)						
Validated questionnaires							
NIHSS* NIHSS, Baseline Visit Filter NSSPERF = Yes AVERAGE OF NIH Stroke Scale: NSSTOTAL	Mean (SD) / Median (IQR)						
NIHSS, Score: 0-6 NIHSS, Baseline Visit Filter NSSPERF = Yes	N (%)						
NIHSS, Score: 7-15 NIHSS, Baseline Visit Filter NSSPERF = Yes	N (%)						
NIHSS, Score: >15 NIHSS, Baseline Visit Filter NSSPERF = Yes	N (%)						
Modified Rankin Scale (pre-stroke mRS) Pre-stroke modified Rankin Scale AVERAGE OF MRSRES	Mean (SD) / Median (IQR)						
Modified Rankin Scale (pre-stroke mRS) = 0 Pre-stroke modified Rankin Scale Filter MRSPERF = Yes	N (%)						
Modified Rankin Scale (pre-stroke mRS) = 1 Pre-stroke modified Rankin Scale Filter MRSPERF = Yes	N (%)						
Modified Rankin Scale (pre-stroke mRS) = 2 Pre-stroke modified Rankin Scale Filter MRSPERF = Yes	N (%)						
Modified Rankin Scale (pre-stroke mRS) = 3 Pre-stroke modified Rankin Scale Filter MRSPERF = Yes	N (%)						
Modified Rankin Scale (pre-stroke mRS) = 4 Pre-stroke modified Rankin Scale Filter MRSPERF = Yes	N (%)						
Modified Rankin Scale (pre-stroke mRS) = 5 Pre-stroke modified Rankin Scale Filter MRSPERF = Yes	N (%)						
EQ-5D-5L Index Value EQ-5D-5L, Baseline Visit CALCULATE Overall Index Value	Mean (SD) / Median (IQR)						
EQ-5D-5L VAS Health Score EQ-5D-5L, Baseline Visit AVERAGE OF EQQ6RES (SUBJECT'S HEALTH TODAY)	Mean (SD) / Median (IQR)						
EQ-5D-5L Mobility EQ-5D-5L, Baseline Visit AVERAGE OF EQQ1RES (MOBILITY)	Mean (SD) / Median (IQR)						
EQ-5D-5L Self-Care EQ-5D-5L, Baseline Visit AVERAGE OF EQQ2RES (SELF-CARE)	Mean (SD) / Median (IQR)						
EQ-5D-5L Usual Activities EQ-5D-5L, Baseline Visit AVERAGE OF EQQ3RES (USUAL ACTIVITIES)	Mean (SD) / Median (IQR)						

Randomisation		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
EQ-5D-5L Pain Discomfort EQ-5D-5L, Baseline Visit AVERAGE OF EQQ4RES (PAIN / DISCOMFORT)	Mean (SD) / Median (IQR)						
EQ-5D-5L Anxiety Depression EQ-5D-5L, Baseline Visit AVERAGE OF EQQ5RES (ANXIETY / DEPRESSION)	Mean (SD) / Median (IQR)						
VEINES-QOL summary score MEAN AVERAGE OF Baseline, VEINES-QOL/SYM QUESTIONNAIRE: 25 items excluding time of day leg problem is most intense – intrinsic scoring method as per Bland et al., 2015	Mean (SD) / Median (IQR)						
VEINES-Sym score MEAN AVERAGE OF Day 90 Visit/End of Study, VEINES-QOL/SYM QUESTIONNAIRE: subset questions 1a to 1i (1.1 – 1.9) and 7.	Mean (SD) / Median (IQR)						

Please note: -randomisation stratification variable indicated by (*) – stroke pathology, NIHSS. Final randomisation stratification is study centre.

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3a. Clinical characteristics at day 7

Day 7		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of participants at randomisation	N						
Number of participants deceased at day 7	N						
Number of participants with data at day 7*	%						
Number of days post-randomisation LLVU Date = LLVU, Day 7: LLVUDAT OR LLVU Short, Day 7 Visit: LLVU_DATE_1_ [LLVU Date] – [RAND, Randomisat_CREATE_DTM]	Median; Max; Min						
Compression Doppler LLVU, Day 7 Visit Filter LLVUYN = Yes COUNT OF LLVUDAT (Date of Doppler) LLVU Short, Day 7 Visit Filter LLVU_PERFORMED____1_ = Yes COUNT OF LLVU_DATE_1_	N (%)						
NIHSS NIHSS, Day 7 Visit Filter NSSPERF = Yes AVERAGE OF NIH Stroke Scale: NSSTOTAL	Mean (SD) / Median (IQR)						
NIHSS, Score: 0-6 NIHSS, Day 7 Visit Filter NSSPERF = Yes	N (%)						
NIHSS, Score: 7-15 NIHSS, Day 7 Visit Filter NSSPERF = Yes	N (%)						
NIHSS, Score: >15 NIHSS, Day 7 Visit Filter NSSPERF = Yes	N (%)						

*Any data point

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3b. Clinical characteristics at Day 14

Day 14		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of participants at randomisation	N						
Number of participants deceased at day 14	N						
Number of participants with data at day 14	%						
Number of days post-randomisation LLVU Date = LLVU, Day 14: LLVUDAT OR LLVU Short, Day 14 Visit: LLVU_DATE_1_ [LLVU Date] – [RAND, Randomisat_CREATE_DTM]	Median; Max; Min						
Compression Doppler LLVU, Day 14 Filter LLVUYN = Yes COUNT OF LLVUDAT (Date of Doppler) LLVU Short, Day 14 Visit Filter LLVU_PERFORMED___1_ = Yes COUNT OF LLVU_DATE_1_	N (%)						
NIHSS NIHSS, Day 14 Visit Filter NSSPERF = Yes AVERAGE OF NIH Stroke Scale: NSSTOTAL	Mean (SD) / Median (IQR)						
NIHSS, Score: 0-6 NIHSS, Day 7 Visit Filter NSSPERF = Yes	N (%)						
NIHSS, Score: 7-15 NIHSS, Day 7 Visit Filter NSSPERF = Yes	N (%)						
NIHSS, Score: >15 NIHSS, Day 7 Visit Filter NSSPERF = Yes	N (%)						

*Any data point

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3c. Clinical characteristics summary of Day 14 (V3.0)/ Day 30 (V2.0)

Day 14 / [Day 30]		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of participants at randomisation	N						
No of patients deceased by day 14	N						
Number of participants with data – Protocol V2.0 @Day30	N (%)						
Number of participants with data – Protocol V3.0 @Day14	N (%)						
30d Discharge Questions Day 14 Data Collection							
Decompressive craniectomy COUNT OF 14DDCRAN = Yes AND COUNT OF 30DDCRAN = Yes	N (%)						
Surgery for intracranial haemorrhage COUNT OF 14DSURG = Yes AND COUNT OF 30DSURG = Yes	N (%)						
Intensive Care (days) AVERAGE OF 14DICUNM = Yes AND 30DICUNM = Yes	N (%)						
Final diagnosis Day 14 Data Collection 30d Discharge Questions							
Cerebral infarct COUNT OF 14DFDIAG = cerebral infarct AND COUNT OF 30DFDIAG = Cerebral infarct	N (%)						
Intracerebral haemorrhage COUNT OF 14DFDIAG = Intracerebral haemorrhage AND COUNT OF 30DFDIAG = Intracerebral haemorrhage	N (%)						
Clinical diagnosis of stroke / no imaging done COUNT OF 14DFDIAG = Clinical diagnosis of stroke / no imaging done AND COUNT OF 30DFDIAG = Clinical diagnosis of stroke / no imaging done	N (%)						
Transient ischaemic attack COUNT OF 14DFDIAG = Transient ischaemic attack AND COUNT OF 30DFDIAG = Transient ischaemic attack	N (%)						
Not a stroke COUNT OF 14DFDIAG = Not a stroke AND COUNT OF 30DFDIAG = Not a stroke	N (%)						

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3d. Clinical characteristics at Day 30 (V2.0 and V3.0)

Day 30		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of participants at randomisation	N						
Number of participants with Day 30 data - Protocol V2.0 and V3.0	N						
No of patients deceased by day 30	N (%)						
Stroke recurrence 30d Discharge Questions 30d Questions COUNT OF 30DSREC = Yes	N (%)						
Covid-19 infection since admission COVID-19 Status, Day 30 Visit COUNT OF CV19SAYN = Yes	N (%)						
On antiplatelets during hospital stay 30d Questions COUNT OF HOSPITAL_ANTIPLATELETS= Yes	N (%)						
Number of days on antiplatelets during hospital stay 30d Questions AVERAGE OF HOSPITAL_AP_DAYS	Mean (SD) + percentage of length of in-patient days						
On prophylactic dose of anticoagulant during hospital stay 30d Questions COUNT OF HOSPITAL_PAC = Yes	N (%)						
Number of days on prophylactic dose of anticoagulant during hospital stay 30d Questions AVERAGE OF HOSPITAL_PAC_DAYS	Mean (SD) + percentage of length of in-patient days						
On full dose of anticoagulant during hospital stay 30d Questions COUNT OF HOSPITAL_FDAC = Yes	N (%)						
Number of days on full dose of anticoagulant during hospital stay 30d Questions AVERAGE OF HOSPITAL_FDAC_DAYS	Mean (SD) + percentage of length of in-patient days						
On antiplatelets at hospital discharge 30d Questions COUNT OF DISCHARGE_ANTIPLATELETS = Yes	N (%)						
On prophylactic dose of anticoagulant at discharge 30d Questions COUNT OF DISCHARGE_PAC = Yes	N (%)						
On full dose of anticoagulant at hospital discharge 30d Questions COUNT OF DISCHARGE_FDAC = Yes	N (%)						
Patient was transferred to another ward or hospital for ongoing care 30d Questions COUNT OF _30D_TRANSFER = Yes	N (%)						
Patient was discharged into the community 30d Questions COUNT OF _30D_DISCHARGE_COMMUNITY = Yes	N (%)						

Day 30		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Discharge destination – private residence 30d Questions COUNT OF _30D_DISCHARGE_DESTINATION = private residence	N (%)						
Discharge destination – care home 30d Questions COUNT OF _30D_DISCHARGE_DESTINATION = Care home	N (%)						

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3e. Clinical characteristics at Day 90

Day 90		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of participants at randomisation	N						
Number of participants with data at Day 90	N (%)						
Vital Status at Day 90							
Death Study Level Forms, Adverse Events COUNT OF AEOUT = Death	N (%)						
Other health condition COUNT OF 90DQQ1 = Other health condition	N (%)						
VTEs – since discharge up to day 90 90d Questionnaire							
No DVT/PE COUNT OF 90DQQ1 = No	N (%)						
Clinical incidence – any DVT or PE							
Clinical incidence – DVT COUNT OF 90DQQ1 = DVT/blood clot in leg	N (%)						
Clinical incidence – PE COUNT OF 90DQQ1 = PE/blood clot in lung	N (%)						
Clinical incidence – DVT, symptomatic COUNT OF 90DQQ2_3 = Yes, Symptomatic	N (%)						
Clinical incidence – DVT, asymptomatic COUNT OF 90DQQ2_3 = No, Asymptomatic	N (%)						
Clinical incidence – DVT, do not remember COUNT OF 90DQQ2_3 = Do not remember	N (%)						
Clinical incidence – DVT, Not recorded COUNT OF 90DQQ2_3 = Not recorded	N (%)						
DVT in Left Leg COUNT OF 90DQQ2_4 = Left	N (%)						
DVT in Right Leg COUNT OF 90DQQ2_4 = Right	N (%)						
DVT in Both Legs COUNT OF 90DQQ2_4 = Both	N (%)						
Clinical incidence - PE, symptomatic COUNT OF 90DQQ3_3 = Yes, Symptomatic	N (%)						
Clinical incidence - PE, asymptomatic COUNT OF 90DQQ3_3 = No, Asymptomatic	N (%)						
Clinical incidence – PE, do not remember COUNT OF 90DQQ3_3 = Do not remember	N (%)						
Post discharge medications							
Are they taking any antiplatelets now? None COUNT OF 90DANTIP = None	N (%)						
Are they taking any antiplatelets now? Aspirin COUNT OF 90DANTIP = Aspirin	N (%)						
Are they taking any antiplatelets now? Clopidogrel COUNT OF 90DANTIP = Clopidogrel	N (%)						
Are they taking any antiplatelets now? Dipyridamole COUNT OF 90DANTIP = Dipyridamole	N (%)						
Are they taking any antiplatelets now? Colistazole COUNT OF 90DANTIP = Colistazole	N (%)						
Are they taking any antiplatelets now? Ticagrelor COUNT OF 90DANTIP = Ticagrelor	N (%)						

Day 90		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Are they taking any antiplatelets now? Other antiplatelet agent COUNT OF 90DANTIP = Other antiplatelet agent	N (%)						
Are they taking any anticoagulants now? None COUNT OF _90DQ_QUESTION_3A = None	N (%)						
Are they taking any anticoagulants now? Warfarin COUNT OF _90DQ_QUESTION_3A = Warfarin	N (%)						
Are they taking any anticoagulants now? Apixaban COUNT OF _90DQ_QUESTION_3A = Apixaban	N (%)						
Are they taking any anticoagulants now? Enoxaparin COUNT OF _90DQ_QUESTION_3A = Enoxaparin	N (%)						
Are they taking any anticoagulants now? Rivaroxaban COUNT OF _90DQ_QUESTION_3A = Rivaroxaban	N (%)						
Are they taking any anticoagulants now? Dabigatran COUNT OF _90DQ_QUESTION_3A = Dabigatran	N (%)						
Are they taking any anticoagulants now? Injected dalteparin COUNT OF _90DQ_QUESTION_3A = Injected dalteparin	N (%)						
Are they taking any anticoagulants now? Injected heparin COUNT OF _90DQ_QUESTION_3A = Injected heparin	N (%)						
Are they taking any anticoagulants now? Other injected blood thinner COUNT OF _90DQ_QUESTION_3A = Other injected blood thinner	N (%)						
Since the stroke, Antiplatelet started COUNT 90DQQ4 = Antiplatelet agent started	N (%)						
Since the stroke, Antiplatelet stopped COUNT 90DQQ4 = Antiplatelet agent stopped	N (%)						
Since the stroke, Anticoagulants started COUNT 90DQQ4 = Anticoagulant started	N (%)						
Since the stroke, Anticoagulants stopped COUNT 90DQQ4 = Anticoagulant stopped	N (%)						
Since the stroke, Other new medication started (blood thinners) COUNT 90DQQ4 = Other new medication started	N (%)						
Readmittance							
Readmittance to hospital – Yes COUNT OF 90DQQ6 = Yes	N (%)						
Readmittance to hospital – No COUNT OF 90DQQ6 = No	N (%)						
Readmittance to hospital – No – still in hospital COUNT OF 90DQQ6 = No – still in Hospital/Acute Stroke Unit	N (%)						
Readmittance to hospital – No – still in rehab unit COUNT OF 90DQQ6 = No – still in Rehabilitation Unit	N (%)						
Patient specific questions							
Leg Pain AVERAGE OF 90DQQ8	Mean (SD)						
Reported Skin Breaks – None COUNT OF 90DQQ9= None	N (%)						

Day 90		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Reported Skin Breaks – Right Leg COUNT OF 90DQQ9 = Right Leg	N (%)						
Reported Skin Breaks – Left Leg COUNT OF 90DQQ9 = Left Leg	N (%)						
Reported Skin Breaks – Both Legs COUNT OF 90DQQ9 = Both Legs	N (%)						
Skin breaks better since the stroke COUNT OF 90DQQ9_1 = Better since the stroke	N (%)						
Skin breaks worse since the stroke COUNT OF 90DQQ9_1 = Worse since the stroke	N (%)						
Skin breaks same as before the stroke COUNT OF 90DQQ9_1 = Same as before the stroke	N (%)						
Current Residence – Private residence COUNT OF 90DQQ10 = Private residence	N (%)						
Current Residence – Care Home COUNT OF 90DQQ10 = Care Home	N (%)						
Current Residence - Still in hospital / acute stroke unit COUNT OF 90DQQ10 = Still in hospital / acute stroke unit	N (%)						
Current Residence - Still in rehabilitation unit COUNT OF 90DQQ10 = Still in rehabilitation unit	N (%)						
Current Residence – Other COUNT OF 90DQQ10 = Other	N (%)						
Changed residence since discharge? COUNT OF 90DQQ11 = Yes	N (%)						
Residence Before - Private residence COUNT OF 90DQQ12 = Private residence	N (%)						
Residence Before - Care Home COUNT OF 90DQQ12 = Care Home	N (%)						
Residence Before - hospital / acute stroke unit COUNT OF 90DQQ12 = Still in hospital / acute stroke unit	N (%)						
Residence Before - rehabilitation unit COUNT OF 90DQQ12 = rehabilitation unit	N (%)						
Residence Before – Other COUNT OF 90DQQ12 = Other	N (%)						

Day 90		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
<p>Home time (calculated, days)</p> <p>HT was the number of full days not in hospital and where discharge destination was same as at admission (including where care-home was the prestroke residence). Where final follow-up occurred early, last known placement was extrapolated to 90 days. Patients with unknown dates of placement were excluded from the analysis. Patients who died prior to hospital discharge / withdrew fully prior to 90 days were excluded from the analysis.</p> <p>CALCULATE: [Visit Information Day 90 Visit/End of Study, SVDDAT (Actual Date of Discharge)]* - [Baseline Visit, Baseline Medical History and Concomitant Medication Status: MHSPDAT (Date of hospital admission)] - [DATEDIF(90DQ7_A,90DQ7_B)] (days re-admitted)</p> <p>WHERE Baseline Medical History and Concomitant Medication Status, MHLOC (Residence prior to admission) = 90d Questionnaire, 90DQ10 (Current place of residence)</p> <p>*If Day 90 Visit/End of Study not available, use Day 30 Visit, 30d Questions: _30D_DISCHARGE_DATE (Discharge date).</p>	Mean (SD)						
Questionnaires							
<p>Simplified modified Rankin Scale questionnaire</p> <p>90d Modified Rankin Score by Telephone</p> <p>MEAN AVERAGE OF MRS2RES</p>	Mean (SD) / Median (IQR)						
mRS change from baseline							
<p>VEINES-QOL summary score</p> <p>MEAN AVERAGE OF</p> <p>Day 90 Visit/End of Study, VEINES-QOL/SYM QUESTIONNAIRE: 25 items excluding time of day leg problem is most intense – intrinsic scoring method as per Bland et al., 2015</p>	Mean (SD) / Median (IQR)						
VEINES-QOL summary score, change from baseline							
<p>VEINES-Sym score</p> <p>MEAN AVERAGE OF</p> <p>Day 90 Visit/End of Study, VEINES-QOL/SYM QUESTIONNAIRE: subset questions 1a to 1i (1.1 – 1.9) and 7.</p>	Mean (SD) / Median (IQR)						
VEINES- Sym score, change from baseline							
<p>EQ-5D-5L Index Value (inclusive of death)</p> <p>Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version</p> <p>CALCULATE Overall Index Value</p>	Mean (SD) / Median (IQR)						
<p>EQ-5D-5L Index Value (exclusive of death)</p> <p>Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version</p> <p>CALCULATE Overall Index Value</p>	Mean (SD) / Median (IQR)						

Day 90		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
EQ-5D-5L VAS Health Score Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version AVERAGE OF EQQ6RES (SUBJECT'S HEALTH TODAY)	Mean (SD) / Median (IQR)						
EQ-5D-5L Mobility Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version AVERAGE OF EQQ1RES (MOBILITY)	Mean (SD) / Median (IQR)						
EQ-5D-5L Self-Care Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version AVERAGE OF EQQ2RES (SELF-CARE)	Mean (SD) / Median (IQR)						
EQ-5D-5L Usual Activities Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version AVERAGE OF EQQ3RES (USUAL ACTIVITIES)	Mean (SD) / Median (IQR)						
EQ-5D-5L Pain Discomfort Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version AVERAGE OF EQQ4RES (PAIN / DISCOMFORT)	Mean (SD) / Median (IQR)						
EQ-5D-5L Anxiety Depression Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version AVERAGE OF EQQ5RES (ANXIETY / DEPRESSION)	Mean (SD) / Median (IQR)						

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3f. Other outcomes at Day 90

Source of Day 90 data		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of participants at randomisation	N						
Number of participants with data at Day 90	N (%)						
<i>Source of information:</i> 90d Questionnaire							
Participant COUNT OF _90DQ_DATA_SOURCE = Participant COUNT OF _90DQ_DATA_SOURCE = [Blank]	N (%)						
Personal Consultee/Alternative contact person COUNT OF _90DQ_DATA_ = Personal Consultee/Alternative contact person	N (%)						
Carer/Close relative/Friend COUNT OF _90DQ_DATA_SOURCE = Carer/Close relative/Friend	N (%)						
GP/GP Notes COUNT OF _90DQ_DATA_SOURCE = GP/GP Notes	N (%)						
Participant Medical Notes COUNT OF _90DQ_DATA_SOURCE = Participant Medical Notes	N (%)						
Hospital Episode Statistics COUNT OF _90DQ_DATA_SOURCE = Hospital Episode Statistics	N (%)						

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3g. Device Feedback at Day 14 (V3.0) / Day 30 (V2.0)

		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of participants at randomisation							
Number of participants with data - Protocol V2.0 @Day 30 COUNT OF DDIPERF = Yes	N (%)						
Number of participants with data - Protocol V3.0 @Day 14 COUNT OF DDIPERF = Yes	N (%)						
Device acceptability questionnaire – Patient feedback Day 14 Visit, Device Acceptability Questionnaire Day 30 Visit, Discharge Device Information and Acceptability							
Patient found device very comfortable COUNT OF DDIQ1 = Very comfortable	N (%)						
Patient found device comfortable COUNT OF DDIQ1 = Comfortable	N (%)						
Patient found device uncomfortable COUNT OF DDIQ1 = Uncomfortable	N (%)						
Patient found device very uncomfortable COUNT OF DDIQ1 = Very uncomfortable	N (%)						
Patient found device extremely uncomfortable COUNT OF DDIQ1 = Extremely uncomfortable	N (%)						
Patient unable to respond to device comfort COUNT OF DDIQ1 = N/A - unconscious	N (%)						
Skin irritation COUNT OF DDIQ2 = Yes	N (%)						
Patient slept with device COUNT OF DDIQ3 = Yes	N (%)						
Patient slept better with device COUNT OF DDIQ4 = Sleep better	N (%)						
Patient's sleep was not affected by device COUNT OF DDIQ4 = Sleep not affected	N (%)						
Patient's sleep was affected a little bit by the device COUNT OF DDIQ4 = It affected my sleep a little bit	N (%)						
Patient was kept awake most of the night by the device COUNT OF DDIQ4 = The device kept me awake most of the night	N (%)						
Patient unable to respond to impact on sleep COUNT OF DDIQ4 = N/A – unconscious	N (%)						
Patient could not tolerate device (Q5 answered) due to:							
Discomfort COUNT OF DDIQ5 = Discomfort	N (%)						
Skin irritation COUNT OF DDIQ5 = Skin irritation	N (%)						
Affecting sleep COUNT OF DDIQ5 = Affecting sleep	N (%)						
Pain COUNT OF DDIQ5 = Pain	N (%)						
Diarrhoea COUNT OF DDIQ5 = Diarrhoea	N (%)						
Too hot COUNT OF DDIQ5 = Too hot	N (%)						

		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Risk of falls COUNT OF DDIQ5 = Risk of falls	N (%)						
Fall COUNT OF DDIQ5 = Fall	N (%)						
Confusion or restlessness COUNT OF DDIQ5 = Confusion or restlessness	N (%)						
Other COUNT OF DDIQ5 = Other	N (%)						
Device acceptability questionnaire – Nurse feedback							
Day 14 Visit, Device Acceptability Questionnaire							
Day 30 Visit, Discharge Device Information and Acceptability							
Level of mobility – bedbound COUNT OF DDIQ6 = bedbound (out of bed less than once a day)	N (%)						
Level of mobility – requires hoist to transfer to chair COUNT OF DDIQ6 = Requires a hoist to transfer to a chair	N (%)						
Level of mobility – requires assistance to transfer to chair COUNT OF DDIQ6 = Needs assistance to transfer to chair	N (%)						
Level of mobility – mobile with assistance COUNT OF DDIQ6 = Mobile with assistance	N (%)						
Level of mobility – independently mobile COUNT OF DDIQ6 = Independently mobile	N (%)						
Ease of device application – Very easy COUNT OF DDIQ7 = Very easy	N (%)						
Ease of device application – Easy COUNT OF DDIQ7 = Easy	N (%)						
Ease of device application – Difficult COUNT OF DDIQ7 = Difficult	N (%)						
Ease of device application – Very Difficult COUNT OF DDIQ7 = Very Difficult	N (%)						
Ease of device application – Not possible COUNT OF DDIQ7 = Not possible	N (%)						
Ease of fitting instructions – Very easy COUNT OF DDIQ8 = Very easy	N (%)						
Ease of fitting instructions – Easy COUNT OF DDIQ8 = Easy	N (%)						
Ease of fitting instructions – Difficult COUNT OF DDIQ8 = Difficult	N (%)						
Ease of fitting instructions – Very difficult COUNT OF DDIQ8 = Very Difficult	N (%)						
Ease of fitting instructions – Not possible COUNT OF DDIQ8 = Not possible	N (%)						
Ease of re-applying device after showering – Yes (Easy) COUNT OF DDIQ14 = Yes	N (%)						
Ease of re-applying device after showering – N/A COUNT OF DDIQ14 = N/A	N (%)						
Use of Devices							
Device Information & Log							
Day 30 Visit, Discharge Device Information and Acceptability							
Number of days device worn (days) MEAN AVERAGE OF DDIQ16	Mean (SD) / Median (IQR)						

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3h. Other data points

		No Intervention Group		Intervention Group		Total	
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)
Number of participants at randomisation	N						
Study Exit							
Study Exit Form							
Number of participants with data	N (%)						
Patient completed according to protocol COUNT OF EOSREAS = Completed Study (according to protocol)	N (%)						
Withdrawal – patient; full withdrawal from study COUNT OF EOSREAS = full withdrawal from study	N (%)						
Withdrawal – patient; withdraw from further contact but can obtain data from other sources COUNT OF EOSREAS = Withdrawal – patient; withdraw from further contact...	N (%)						
Withdrawal – Investigator decision COUNT OF EOSREAS = Withdrawal – Investigator decision	N (%)						
Death COUNT OF EOSREAS = Death	N (%)						
Loss to Follow-up COUNT OF EOSREAS = Loss to follow-up – only complete at end of trial	N (%)						
Screen Failure COUNT OF EOSREAS = Screen Failure	N (%)						
Other COUNT OF EOSREAS = Other	N (%)						
Re-Consent / Declaration							
Informed Consent Log							
Number of participants with data	N (%)						
Subject Reconsented COUNT OF ICLRCBY = Subject	N (%)						
Personal Consultee Declaration COUNT OF ICLRCBY = Personal Consultee	N (%)						
Nominated Consultee Declaration COUNT OF ICLRCBY = Nominated Consultee	N (%)						
Co-enrolment							
Number of participants with data	N (%)						
Patient co-enrolled COUNT OF CO_ENROL_Q = Yes	N (%)						
Co-enrolment with Study #1 COUNT OF CO_ENROL_DETAILS	N (%)						
Co-enrolment with Study #2 COUNT OF CO_ENROL_DETAILS	N (%)						

Co-enrolment with Study #3 COUNT OF CO_ENROL_DETAILS	N (%)						
Co-enrolment with Study #4 COUNT OF CO_ENROL_DETAILS	N (%)						

Please Note: Studies will be added as co-enrolment agreements are put in place.

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3i. Primary outcomes

Outcomes		No Intervention Group		Intervention Group		Total		Appropriate regression model			
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	Point estimate	80% CI	95% CI	p-value
Number of participants at randomisation											
Number of participants at Day 30	N (%)										
Primary outcome - Any symptomatic or asymptomatic DVT in the calf, popliteal or femoral veins or any PE within 30 days of randomisation (yes or no)											
30d Discharge Questions / 30d Questions COUNT OF 30DDVTTY = Symptomatic AND COUNT OF 30DDVTTY = Asymptomatic	N (%)										
IF NOT INCLUDED ABOVE, Day 7 LLVU COUNT OF LLVURES = POSITIVE FOR DVT AND COUNT OF LLVURES = POSITIVE FOR DVT	N (%)										
IF NOT INCLUDED ABOVE, Day 14 LLVU COUNT OF LLVURES = POSITIVE FOR DVT AND COUNT OF LLVURES = POSITIVE FOR DVT	N (%)										
IF NOT INCLUDED ABOVE, Day 7 LLVU Short COUNT OF LLVU_RIGHT_DVT = POSITIVE FOR DVT AND COUNT OF LLVU_LEFT_DVT = POSITIVE FOR DVT	N (%)										
IF NOT INCLUDED ABOVE, Day 14 LLVU Short COUNT OF LLVU_RIGHT_DVT = POSITIVE FOR DVT AND COUNT OF LLVU_LEFT_DVT = POSITIVE FOR DVT	N (%)										
30d Discharge Questions / 30d Questions COUNT OF 30DPETYP = Symptomatic AND COUNT OF 30DPETYP = Asymptomatic	N (%)										
IF NOT INCLUDED IN ROW ABOVE, AE COUNT OF AETERM = "embolism"/"PE" CONDITIONAL: [Study Level Forms, Adverse Events, AEENDAT (AE End Date)] - [Date of Randomisation CREATE DATE (Date of Randomisation)] =<33	N (%)										
30d Discharge Questions / 30d Questions SUM OF Previous 7 rows	N (%)										

Outcomes		No Intervention Group		Intervention Group		Total		Appropriate regression model			
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	Point estimate	80% CI	95% CI	p-value
Days to VTE incidence within 30 days Calculate AVERAGE: 30d Discharge Questions/30d Questions: 30DDAT [Date of DVT Diagnosis] – Randomisat_CREATE_DTM [Date of Randomisation] 30d Discharge Questions/30d Questions: 30DPEDAT [Date of PE Diagnosis] – [Date of Randomisation CREATE DATE] If not above, AE for “Pulmonary Embolism”: AESTDAT [event occur/start?] – Randomisat_CREATE_DTM [Date of Randomisation]	Mean (SD) / Median (IQR)										
30d DVT - Symptomatic 30d Discharge Questions / 30d Questions COUNT OF COUNT OF 30DDVTY = Symptomatic	N (%)										
30d DVT - Asymptomatic 30d Discharge Questions / 30d Questions COUNT OF 30DDVTY = Asymptomatic	N (%)										
Day 7 LLVU, chronic DVT noted COUNT OF Day 7 LLVU: LLVU_COMMENTS__R_ = chronic AND / OR Day 7 LLVU: LLVU_COMMENTS__L_ = chronic	N (%)										
Day 14 LLVU, chronic DVT cases noted COUNT OF Day 14 LLVU: LLVU_COMMENTS__R_ = chronic AND / OR Day 14 LLVU: LLVU_COMMENTS__L_ = chronic	N (%)										
30d PE - Symptomatic 30d Discharge Questions / 30d Questions COUNT OF COUNT OF 30DPETYP = Symptomatic	N (%)										
30d PE - Asymptomatic 30d Discharge Questions / 30d Questions COUNT OF COUNT OF 30DPETYP = Symptomatic	N (%)										

Please note: The scores include the n patients that have died by day 30

Greyed boxes indicate where regression is not applicable.

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3j. Secondary outcomes

Outcomes		No Intervention Group		Intervention Group		Total		Appropriate regression model			
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	Point estimate	80% CI	95% CI	p-value
Number of participants at randomisation											
Number of participants at Day 14	N (%)										
Number of participants at Day 30	N (%)										
Secondary outcomes at 14 days after randomisation											
1a. Patient could not tolerate device Day 14 Visit, Device Acceptability Questionnaire COUNT OF DDIQ5 = ALL ANSWERS excluding "Not Applicable" AND Day 30 Visit, Discharge Device Information and Acceptability COUNT OF DDIQ5 = ALL ANSWERS excluding "Not Applicable" CONDITIONAL: [Visit Information, Day 30 Visit, SVDAT (Date of Day 30 Visit)] - [Date of Randomisation CREATE DATE (Date of Randomisation)] =<17 [Populated by Firstkind to ensure blinding]	N (%)										
Secondary outcomes at 30 days after randomisation											
1b. Adherence to allocated treatment Device Information & Log / Day 30 Visit, Discharge Device Information and Acceptability COUNT ALL where DDIQ15 = 0 (30d question How many times was the device checked and found to not be in place or not working properly?)	N (%)										
1c. Death from any cause Study Level Forms, Adverse Events COUNT OF AEOUT = Death CONDITIONAL: [Study Level Forms, Adverse Events, AEENDAT (AE End Date)] - [Date of Randomisation CREATE DATE (Date of Randomisation)] =<33	N (%)										
1d. Confirmed fatal or non-fatal PE 30d Discharge Questions / 30d Questions COUNT OF COUNT OF 30DPETYP = Symptomatic AND 30d Discharge Questions / 30d Questions COUNT OF COUNT OF 30DPETYP = Asymptomatic OR Study Level Forms, Adverse Events COUNT OF AETERM* = "Pulmonary embolism"/"PE" CONDITIONAL: [Study Level Forms, Adverse Events, AEENDAT (AE End Date)] - [Date of Randomisation CREATE DATE (Date of Randomisation)] =<33	N (%)										
1e. Any (symptomatic or asymptomatic) above knee DVT 30d Discharge Questions / 30d Questions COUNT OF 30DDVTTY = Symptomatic AND COUNT OF 30DDVTTY = Asymptomatic Filter: _30D_DVT_LOCATION = "Above knee DVT"	N (%)										

Outcomes		No Intervention Group		Intervention Group		Total		Appropriate regression model			
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	Point estimate	80% CI	95% CI	p-value
1f. Any (symptomatic or asymptomatic) DVT in popliteal or femoral veins and symptomatic calf vein DVT 30d Questions COUNT OF 30DDVTY = Symptomatic AND COUNT OF 30DDVTY = Asymptomatic Filter: _30D_DVT_LOCATION = "Above knee DVT" and "Popliteal DVT" AND 30d Questions COUNT OF 30DDVTY = Symptomatic Filter: _30D_DVT_LOCATION = Below knee DVT AND 30d Discharge Questions COUNT OF 30DDVTY = Symptomatic AND COUNT OF 30DDVTY = Asymptomatic	(%)										
1g. Combined c-e (any VTE or death by day 90)	(%)										
Secondary outcomes at 90 days after randomisation											
2a. Leg pain via Numerical Rating Scale 90d Questionnaire AVERAGE OF 90DQQ8	Mean (SD) / Median (IQR)										
2b. Death from any cause Study Level Forms, Adverse Events COUNT OF AEOUT = Death	(%)										
2c. Any symptomatic or asymptomatic DVT or PE occurring between randomisation and final follow-up Primary Outcome number (page 45) AND [Conditional, IF UNIQUE] 90d Questionnaire COUNT OF 90DQQ1 = DVT/blood clot in leg AND [Conditional, IF UNIQUE] 90d Questionnaire COUNT OF 90DQQ1 = PE/blood clot in lung	(%)										
2d. Combined b and c	(%)										
2e. Disability (modified Rankin Scale) DIFFERENCE: [90d Modified Rankin Score by Telephone MEAN AVERAGE OF MRS2RES] - [Pre-stroke modified Rankin Scale MEAN AVERAGE OF MRSRES]	Mean (SD) / Median (IQR)										

Outcomes		No Intervention Group		Intervention Group		Total		Appropriate regression model			
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	Point estimate	80% CI	95% CI	p-value
2f. Health related quality of life (EQ-5D-5L, Index Score) Day 90 Visit/End of Study, EQ-5D-5L and EQ-5D-5L Interviewer version CALCULATE Overall Index Value	Mean (SD) / Median (IQR)										
2g. Place of residence after discharge 90d Questionnaire COUNT OF 90DQQ12 = Private residence COUNT OF 90DQQ12 = Care Home COUNT OF 90DQQ12 = Still in hospital / acute stroke unit COUNT OF 90DQQ12 = rehabilitation unit COUNT OF 90DQQ12 = Other	(%)										

Greyed boxes indicate where regression is not applicable.

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3k. Exploratory/Health Economic Outcomes

Outcomes		No Intervention Group		Intervention Group		Total		Appropriate regression model			
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	Point estimate	80% CI	95% CI	p-value
Number of participants at randomisation											
Number of participants at Day 7	N (%)										
Number of participants at Day 14	N (%)										
Number of participants at Day 30	N (%)										
Number of participants at Day 90	N (%)										
Exploratory/Health Economic outcomes at 7 days after randomisation											
3a. Early neurological recovery, NIHSS NIHSS, Day 7 Visit and NIHSS, Baseline Filter NSSPERF = Yes DIFFERENCE:[AVERAGE OF NIH Stroke Scale: NSSTOTAL @Day 7 visit] - [AVERAGE OF NIH Stroke Scale: NSSTOTAL @Baseline]	Mean (SD) / Median (IQR)										

Exploratory/Health Economic outcomes at 14 days after randomisation											
3b. Neurological recovery, NIHSS NIHSS, Day 14 Visit and NIHSS, Baseline Filter NSSPERF = Yes DIFFERENCE: [AVERAGE OF NIH Stroke Scale: NSSTOTAL @Day 14 visit] - [AVERAGE OF NIH Stroke Scale: NSSTOTAL @Baseline] Where Day 14 NIHSS not available, use Day 7 NIHSS if available. NIHSS, Day 7 Visit and NIHSS, Baseline Filter NSSPERF = Yes DIFFERENCE:[AVERAGE OF NIH Stroke Scale: NSSTOTAL @Day 7 visit] - [AVERAGE OF NIH Stroke Scale: NSSTOTAL @Baseline]	Mean (SD) / Median (IQR)										
Exploratory/Health Economic outcomes at 30 days after randomisation											
3c. Stroke recurrence (new infarct or bleed on imaging or NIHSS increase of 8 points or more without confirmation by imaging) 30d Discharge Questions 30d Questions COUNT OF 30DSREC = Yes	(%)										
Exploratory/Health Economic outcomes at 90 days after randomisation											
3d. Length of hospital stay until discharge into the community [Day 90 Visit/End of Study, Visit Information, Actual Date of Discharge: SV, SVDDAT] – [Baseline Visit, Baseline Medical History and ConMed Status, Date of hospital admission: MHCM, MHSPDAT]	Mean (SD) / Median (IQR)										
3e. Home time (As per calculation in Table 3e)	Mean (SD)										

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 3I. Other Outcomes

Outcomes		No Intervention Group		Intervention Group		Total		Appropriate regression model			
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	Point estimate	80% CI	95% CI	p-value
Number of participants at randomisation											
Number of participants at Day 14	N (%)										
Number of participants at Day 90	N (%)										

Outcomes		No Intervention Group		Intervention Group		Total		Appropriate regression model			
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	Point estimate	80% CI	95% CI	p-value
Secondary outcomes at 14 days after randomisation											
Change in NIHSS = 0											
Change in NIHSS = 1-4											
Change in NIHSS = 5-8											
Change in NIHSS > 8											
Change in NIHSS = - 1 to -4											
Change in NIHSS = -5 to -8											
Change in NIHSS > -8											
Secondary outcomes at 90 days after randomisation											
Change in mRS = 0	N										
Change in mRS = +1	N										
Change in mRS = +2	N										
Change in mRS = +3	N										
Change in mRS = +4	N										
Change in mRS = +5	N										
Change in mRS = +6 (death)	N										
Change in mRS = -5	N										
Change in mRS = -4	N										
Change in mRS = -3	N										
Change in mRS = -2	N										
Change in mRS = -1	N										

Boxes greyed out are not applicable

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 4. Adverse events up to Day 30

Adverse events by day 30		No Intervention Group		Intervention Group		Total		
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	
Number of participants at randomisation	N							

Adverse events by day 30		No Intervention Group		Intervention Group		Total		
Variable	Statistic	N (n/N)	Data n(%)	N (n/N)	Data n(%)	N (n/N)	Data n(%)	
Number of participants at Day 30	N (%)							
Further stroke (Infarct)	N (%)							Nervous System Stroke recurrence (ischaemic)
Further stroke (Haemorrhage)	N (%)							Nervous System Stroke recurrence (haemorrhagic)
Symptomatic DVT	N (%)							Cardiovascular (DVT)
Symptomatic PE	N (%)							Cardiovascular (PE)
Asymptomatic DVT (acute) – determined by protocol compression Doppler	N (%)							Cardiovascular (DVT)
Asymptomatic DVT - exclusive of protocol compression Doppler	N (%)							Cardiovascular (DVT)
Asymptomatic PE	N (%)							Cardiovascular (PE)
Atrial Fibrillation	N (%)							Cardiovascular (Atrial fibrillation (AF) or atrial flutter)
Pneumonia / Aspiration pneumonia	N (%)							Respiratory (Pneumonia)
Deterioration in condition – no specified cause	N (%)							
Subclinical seizure	N (%)							Neurological (seizure)
Emphysema	N (%)							Respiratory (other)
Incidental lung nodule	N (%)							Respiratory (other)
Skin irritation / rash	N (%)							Muskuloskeletal /Cutaneous (skin irritation/rash)
Any serious adverse event that is NOT a known complication of stroke and not listed above	N (%)							

Note: This table contains the number of events, patients may have had more than one event.

n/N: n = completed responses / N = number randomised to arm (total)

n(%): percentage out of n (n = percentage out of available data received)

Table 5. Serious adverse events – relationship to study treatment

	No Intervention Group	Intervention Group	Total
All patients	N =	N =	N =
Number of SAEs			
Number of SAEs thought to be related to treatment			
Unlikely			
Possibly			
Probably			
Causal Relationship			

Note: This table contains the number of events related to study treatment. Patients may have had more than one event. Study treatments include: geko device and IPC.

Table 6. Serious adverse events, by types

All patients	No Intervention Group			Intervention Group			Total		
	N =			N =			N =		
	n	N*	%	n	N*	%	n	N*	%
Total number of Events									
By type									
Cardiovascular									
Deep Vein Thrombosis (DVT)									
Pulmonary embolism (PE)									
Arterial thrombosis (any site)									
Atrial fibrillation (AF) or atrial flutter									
Bradycardia									
Cardiac failure or pulmonary oedema									
Myocardial infarction (STEMI)									
Sudden cardiac death (SCD)									
Nervous system									
Cerebral oedema									
Complication of initial stroke									
Dizziness									
Expansion of intracerebral haemorrhage - without hydrocephalus									
Extension of ischaemic stroke									
Haemorrhagic transformation (of infarct, HTI)									
Intracerebral bleed (recurrent haemorrhagic stroke)									
Intracranial/extracerebral bleed									
Ischaemic stroke, including recurrence									
Neurological deterioration									
Seizure / convulsions									
Stroke - undetermined / no imaging									
Sub-arachnoid haemorrhage									
Subdural haematoma									
Swelling of the original infarct									
Respiratory									
Chest infection									
Pneumonia									
Respiratory tract infection, lower (LRI/LRTI)									
Respiratory tract infection, upper (URI/URTI)									
Gastro-intestinal									
Cholecystitis									
Gastrointestinal bleed									
Gastrointestinal infarction									
Hernia									
Genito-urinary									
Urinary tract infection (UTI)									
Haematological/immunological									
Anaemia									
Angioedema									
Metabolic/Endocrine									
Musculoskeletal/cutaneous									
Cellulitis									
Fall									

All patients	No Intervention Group			Intervention Group			Total		
	N =			N =			N =		
	n	N*	%	n	N*	%	n	N*	%
Gout									
Miscellaneous									
Death due to frailty / old age									
Death unattended									
Extracranial bleeding (not GI haemorrhage)									
Infection (not otherwise specified)									
*Other (please state medical condition)									
^SAE Events without subcategories									

Note: n is the number of events in each category. N* is the number of patients with an event.

Table 7. Serious adverse events listing

AE type	No Intervention Group			Intervention Group			Total		
	SAE description	Study day from onset	Severity	SAE description	Study day from onset	Severity	SAE description	Study day from onset	Severity
[Example] Serious Adverse Event (SAE)							Pneumonia , increased oxygen demand and further deterioration. In agreement with the family was considered for palliative care	6	Severe

Table 8. Adverse Device Effect/SADE/USADE listing

AE type (ADE, SADE, USADE)	No Intervention Group			Intervention Group			Total		
	SAE description	Study day from onset	Severity	SAE description	Study day from onset	Severity	SAE description	Study day from onset	Severity
[Example] Adverse Device Effect (ADE)							Skin tear on left leg of patient near device administrat ion site	29	Mild












GEKO SAP V1.1 FINAL 15DEC2025

Final Audit Report

2025-12-16


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