

# CASE REPORT FORMS

**GAPS**

Patient Initials	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Subject No.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Site no.	<input type="checkbox"/> <input type="checkbox"/>		

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## SCREENING

<b>Screening Date</b> ___/___/___ (DD / MMM / YYYY)
<b>Initials:</b> _____ (If no middle initial please use a dash)
<b>Age:</b> ___
<b>Sex:</b> <input type="checkbox"/> Male <input type="checkbox"/> Female
<b>Operation</b> _____ <b>Department</b> _____ (vascular / general / orthopaedics / urology / neurosurgery / obs & gyn / ENT etc)
<b>Reason for exclusion:</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Age &lt; 18</li> <li><input type="checkbox"/> Unable to give informed consent / Lack of Capacity</li> <li><input type="checkbox"/> Contraindications to low molecular weight heparin (LMWH)</li> <li><input type="checkbox"/> Contraindications to GCS (e.g. peripheral arterial disease, stroke patients, individuals undergoing lower limb surgery) *lower limb surgery alone is not an exclusion only if contraindicated</li> <li><input type="checkbox"/> Documented or known thrombophilia or thrombogenic disorder</li> <li><input type="checkbox"/> Individuals requiring therapeutic anticoagulation</li> <li><input type="checkbox"/> Previous venous thromboembolism (VTE)</li> <li><input type="checkbox"/> Patients having intermittent pneumatic compression (IPC) beyond theatre and recovery</li> <li><input type="checkbox"/> Patients requiring inferior vena cava (IVC) filter</li> <li><input type="checkbox"/> Pregnancy (female participants of reproductive age will be eligible for inclusion in the trial, subject to a negative pregnancy test prior to randomisation)</li> <li><input type="checkbox"/> Patients requiring thromboprophylaxis to be extended beyond discharge</li> <li><input type="checkbox"/> Application of a cast or brace in theatre</li> <li><input type="checkbox"/> Clinician decision (please specify) _____</li> <li><input type="checkbox"/> Declined study (please specify reason if willing) _____</li> <li><input type="checkbox"/> Day case (would not receive LMWH)</li> <li><input type="checkbox"/> Patient missed <input type="checkbox"/> Other (please specify) _____</li> </ul>

## Inclusion / Exclusion Checklist

### Inclusion Criteria

The following criteria <b>MUST</b> be answered YES for participant to be included in the trial (except where NA is appropriate):		Yes	No
1.	Elective surgical inpatients assessed as being at moderate or high risk of VTE according to the widely-used UK Department of Health VTE Risk Assessment for Venous Thromboembolism (or the Trust equivalent based on this form)	<input type="checkbox"/>	<input type="checkbox"/>
2.	Patient age $\geq$ 18 years	<input type="checkbox"/>	<input type="checkbox"/>
3.	Able to give informed consent to participate in the study after reading the patient information	<input type="checkbox"/>	<input type="checkbox"/>
<b>If any of the above criteria is answered NO, the participant is NOT eligible for the trial and must not be included in the study.</b>			

### Exclusion Criteria

The following criteria <b>MUST</b> be answered NO for the participant to be included in the trial:		Yes	No
1.	Is there a contraindication to low molecular weight heparin (LMWH)	<input type="checkbox"/>	<input type="checkbox"/>
2.	Is there a contraindication to GCS, including peripheral arterial disease, stroke patients, individuals undergoing lower limb surgery	<input type="checkbox"/>	<input type="checkbox"/>
3.	Is there a documented or known thrombophilia or thrombogenic disorder	<input type="checkbox"/>	<input type="checkbox"/>
4.	Do they require therapeutic anticoagulation	<input type="checkbox"/>	<input type="checkbox"/>
5.	Have they had a previous venous thromboembolism	<input type="checkbox"/>	<input type="checkbox"/>
6.	Do they require intermittent pneumatic compression (IPC) beyond theatre and recovery	<input type="checkbox"/>	<input type="checkbox"/>
7.	Do they require an inferior vena cava (IVC) filter	<input type="checkbox"/>	<input type="checkbox"/>
8.	Do they require thromboprophylaxis to be extended beyond discharge	<input type="checkbox"/>	<input type="checkbox"/>
9.	Do they intend to apply a cast or brace in theatre	<input type="checkbox"/>	<input type="checkbox"/>
10.	Female only: Is the patient pregnant	<input type="checkbox"/>	<input type="checkbox"/>
<b>If any of the above criteria is answered YES, the participant is NOT eligible for the trial and must not be included in the study.</b>			

Signed \_\_\_\_\_ Dated \_\_\_\_\_

**PATIENT CONSENT**

Participant Informed Consent:

Date participant  
signed written  
consent form:

\_\_\_ / \_\_\_ / \_\_\_

(DD / MMM / YYYY)

Name of person taking informed consent: \_\_\_\_\_

**PREGNANCY (IF FEMALE)** Date of Test

Result

\_\_\_ / \_\_\_ / \_\_\_

(DD / MMM / YYYY)

- N/A - Not of child bearing potential
- Negative
- Positive = DO NOT RANDOMISE

**RANDOMISATION**Participant **Randomisation/Enrolment**

Participant study Number allocated:

\_\_\_\_\_

Treatment Arm

 GCS + LMWH LMWH Alone**GIVE PATIENT QUESTIONNAIRES (BEFORE PT TOLD OF TREATMENT ALLOCATION)**

EQ-5D

Also provide patient with:

- Patient Diary
- Patient Contact Card
- Patient stocking compliance diary

**PATIENT CONTACT FORM**

<b>Title</b> _____
<b>Patient First name</b> _____
<b>Patient First Last name</b> _____
<b>Patient address</b>  <b>Address 1</b> _____ <b>Address 2</b> _____ <b>Address 3</b> _____ <b>Address 4</b> _____ <b>Post code</b> _____
<b>Patient email</b> _____ @ _____ <input type="checkbox"/> <b>Not Collected</b>
<b>Patient telephone no.</b> _____
<b>Patient mobile no.</b> _____
<b>Preferred method of contact for questionnaire</b> <input type="checkbox"/> <b>Online</b> <input type="checkbox"/> <b>Mail</b> <input type="checkbox"/> <b>Telephone</b>

## VISIT 1 BASELINE VTE SCORE

Date of Assessment: \_\_\_ / \_\_\_ / \_\_\_\_\_

(DD / MMM / YYYY)

### Department of Health risk assessment for venous thromboembolism (VTE)

Thrombosis risk	
Patient related	Admission related
<input type="checkbox"/> Active cancer or cancer treatment	<input type="checkbox"/> Significantly reduced mobility for 3 days or more
<input type="checkbox"/> Age >60	<input type="checkbox"/> Hip or knee replacement
<input type="checkbox"/> Dehydration	<input type="checkbox"/> Hip fracture
<input type="checkbox"/> Known thrombophilias*	<input type="checkbox"/> Total anaesthetic & surgical time > 90 minutes
<input type="checkbox"/> Obesity (BMI . 30kg.m <sup>2</sup> )	<input type="checkbox"/> Surgery involving pelvis or lower limb with a total anaesthetic & surgical time > 60 minutes
<input type="checkbox"/> One of more significant medical comorbidities (e.g. heart disease; metabolic endocrine or respiratory pathologies; acute infectious diseases; inflammatory conditions)	<input type="checkbox"/> Acute surgical admission with inflammatory or intra-abdominal condition
<input type="checkbox"/> Personal history* or first degree relative with a history of VTE	<input type="checkbox"/> Critical care admission
<input type="checkbox"/> Use of hormone replacement therapy	<input type="checkbox"/> Surgery with significant reduction in mobility
<input type="checkbox"/> Use of oestrogen-containing therapy	
<input type="checkbox"/> Varicose veins with phlebitis	
<input type="checkbox"/> Pregnancy* or < 6 weeks post partum (see NICE guidance for specific risk factors)	
<b>Final Score</b> _____	

\*If ticked the patient would not be eligible for GAPS.

0 ticks = low risk (not eligible for GAPS) 1 tick = medium risk &amp; &gt;1 tick – high risk (eligible)

Bleeding risk	
Patient related	Admission related
<input type="checkbox"/> Active bleeding	<input type="checkbox"/> Neurosurgery, spinal surgery or eye surgery
<input type="checkbox"/> Acquired bleeding disorders (such as acute liver failure)	<input type="checkbox"/> Other procedure with high bleeding risk
<input type="checkbox"/> Concurrent use of anticoagulants known to increase the risk of bleeding (such as warfarin with INR>2)	<input type="checkbox"/> Lumbar puncture/epidural/spinal anesthesia expected within the next 12 hours
<input type="checkbox"/> Acute stroke	<input type="checkbox"/> Lumbar puncture/epidural/spinal anesthesia expected within the previous 4 hours
<input type="checkbox"/> Thrombocytopenia (platelets< 75x10 <sup>9</sup> /L)	
<input type="checkbox"/> Uncontrolled systolic hypertension (230/120 mmHg or higher)	
<input type="checkbox"/> Untreated inherited bleeding disorders (such as haemophilia and von Willebrand's disease)	

**VISIT 1 BASELINE CAPRINI SCORE**

Date of Assessment: \_\_\_ / \_\_\_ / \_\_\_\_\_

(DD / MMM / YYYY)

<p><b>Add 1 point for each of the following statements that apply now or within the past month</b></p>	<p><b>Add 2 points for each of the following statements that apply</b></p>
<input type="checkbox"/> Age 41 - 60 years	<input type="checkbox"/> Age 61-74 years
<input type="checkbox"/> Minor surgery (less than 45 minutes) is planned	<input type="checkbox"/> Current or past malignancies (excluding skin cancer, but not melanoma)
<input type="checkbox"/> Past major surgery (more than 45 minutes) within the last month	<input type="checkbox"/> Planned major surgery lasting longer than 45 minutes (including laparoscopic and arthroscopic)
<input type="checkbox"/> Visible varicose veins	<input type="checkbox"/> Non-removable plaster cast or mold that has kept you from moving your leg within the last month
<input type="checkbox"/> A history of Inflammatory Bowel Disease (IBD) (for example, Crohn's disease or ulcerative colitis)	<input type="checkbox"/> Tube in blood vessel in neck or chest that delivers blood or medicine directly to heart within the last month (also called central venous access, PICC line, or port)
<input type="checkbox"/> Swollen legs (current)	<input type="checkbox"/> Confined to a bed for 72 hours or more
<input type="checkbox"/> Overweight or obese (Body Mass Index above 25)	
<input type="checkbox"/> Heart attack	<p><b>Add 3 points for each of the following statements that apply</b></p>
<input type="checkbox"/> Congestive heart failure	<input type="checkbox"/> Age 75 or over
<input type="checkbox"/> Serious infection (for example pneumonia)	<input type="checkbox"/> History of blood clots, either Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE)
<input type="checkbox"/> Lung disease (for example emphysema or COPD)	<input type="checkbox"/> Family history of blood clots (thrombosis)
<input type="checkbox"/> On bed rest or restrictive mobility, including a removable leg brace for less than 72 hours	<input type="checkbox"/> Personal or family history of positive blood test indicating an increased risk of blood clotting
<input type="checkbox"/> Other risk factors (1 point each)*** <small>***Additional risk factors not tested in the validation studies but shown in the literature to be associated with thrombosis include BMI above 40, smoking, diabetes requiring insulin, chemotherapy, blood transfusions &amp; length of surgery over 2 hours</small>	
<p><b>Women only: Add 1 point for each of the following statements that apply</b></p>	<p><b>Add 5 points for each of the following statements that apply now or within the past month</b></p>
<input type="checkbox"/> Current use of birth control or hormone replacement therapy (HRT)	<input type="checkbox"/> Elective hip or knee joint replacement surgery
<input type="checkbox"/> Pregnant or had a baby within the last month	<input type="checkbox"/> Broken hip, pelvis or leg
<input type="checkbox"/> History of unexplained stillborn infant, recurrent spontaneous abortion (>3), premature birth with toxemia or growth restricted infant	<input type="checkbox"/> Serious trauma (e.g. multiple broken bones due to fall or an car accident)
<p><b>Caprini Score _____ (calculated by database)</b></p>	<input type="checkbox"/> Spinal cord injury resulting in paralysis <input type="checkbox"/> Experienced a stroke



Date of Assessment: \_\_\_/\_\_\_/\_\_\_

(DD / MMM / YYYY)

**VISIT 1 BASELINE VITAL SIGNS**

Weight: \_\_\_ . \_\_\_ kg Height: \_\_\_ . \_\_\_ m BMI calculated automatically

**BASELINE VISIT DEMOGRAPHIC DATA**

Date of Birth: \_\_\_/\_\_\_/\_\_\_

(DD / MMM / YYYY)

Ethnicity:

<b>White</b>	White British <input type="checkbox"/>	White Irish <input type="checkbox"/>	White Other <input type="checkbox"/>	
<b>Mixed race</b>	White & Black Caribbean <input type="checkbox"/>	White & Black African <input type="checkbox"/>	White & Asian <input type="checkbox"/>	Other mixed background <input type="checkbox"/>
<b>Asian or Asian British</b>	Indian <input type="checkbox"/>	Pakistani <input type="checkbox"/>	Bangladeshi <input type="checkbox"/>	Other Asian background <input type="checkbox"/>
<b>Black or Black British</b>	Caribbean <input type="checkbox"/>	African <input type="checkbox"/>	Black Other <input type="checkbox"/>	
<b>Chinese or other ethnicity</b>	Chinese <input type="checkbox"/>	Other <input type="checkbox"/> (please specify)		

Sex:

 Male  
 Female
Work: Is the patient retired?  Yes  No
 If no, : Worker  employee  self-employed  contractor  director  office holder  
 unemployed  student

Occupation \_\_\_\_\_

**VISIT 1 BASELINE LIFE STYLE**
 Smoker:  Never  Ex-smoker  <1 year  <5 years  > 5 years  
 Current Smoker : \_\_\_\_\_ per day
Alcohol consumption: :  Never  Ex drinker  Current drinker: \_\_\_\_\_ units per weekDiet:  Vegetarian  Low Meat Diet  High Meat Diet (>90g day)Physical Activity level:  Low  Moderate\*\*  Vigorous\*\*\*

\*\*walking/ water aerobics/ ballroom and line dancing/ riding a bike on level ground or with few hills/ playing doubles tennis/ pushing a lawn mower/ canoeing/ volleyball – 150 minutes a week\*\*\*jogging or running/ aerobics/ swimming fast/ riding a bike fast or on hills/ singles tennis/ football/ hiking uphill/ energetic dancing/ martial arts – 75 minutes a week

**VISIT 1 (BASELINE) MEDICATIONS**

<b>Women only : Current use of Oral Contraceptives</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<b>Women only : Current use of Post menopausal hormones</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<b>Anti-Inflammatory Drugs</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<b>Statins</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<b>Currently taking Antiplatelet therapy</b>	<input type="checkbox"/> None <input type="checkbox"/> Single <input type="checkbox"/> Dual <input type="checkbox"/> Triple
<b>Other Medication</b>	<input type="checkbox"/> Others: _____

**VISIT 1 (BASELINE) MEDICAL HISTORY**

<b>History of Malignancy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes if yes _____
<b>Past Surgical History</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes if yes _____
<b>Past Medical History</b>	<input type="checkbox"/> Previous myocardial infarction <input type="checkbox"/> Previous stroke <input type="checkbox"/> Treated hypertension <input type="checkbox"/> Other relevant history _____ <input type="checkbox"/> None
<b>Previous Pregnancies</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes

**VISIT 1 (BASELINE) SURGERY DETAILS**

<b>Actual date of surgery</b>	___/___/___ (DD / MMM / YYYY)
<b>Was the patient still eligible on the date of surgery?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No, please state why _____
<b>Anaesthetic</b>	<input type="checkbox"/> General <input type="checkbox"/> Regional <input type="checkbox"/> Both <input type="checkbox"/> Other
<b>Which stockings were the patient prescribed?</b>	<input type="checkbox"/> N/A – randomised to LMWH alone <input type="checkbox"/> Above knee stocking <input type="checkbox"/> Below knee stocking

SAMPLE

# TELEPHONE FOLLOW UP – PATIENT CONTACT ATTEMPT FORM

Please document all attempts to contact the patient during the 90 day follow-up period	If you could not speak to the patient on this attempt, please document if message left with relative / voicemail / number no longer works etc.
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	
<b>Date of Call</b> ___ / ___ / <b>2 0</b> ___ <small>(DD / MMM / YYYY)</small>  <b>Time of call:</b> ___ : ___ (24:00)	

## FOLLOW-UP VISIT 1 DISCHARGE OR 1 WEEK (WHICHEVER IS EARLIEST)

Date of Assessment: \_\_\_ / \_\_\_ / \_\_\_  
(DD / MMM / YYYY)

Visit  Hospital Discharge  1 week

Visit  In person  Over the telephone

<p>Any VTE symptoms:</p> <p><input type="checkbox"/> <b>None</b></p> <p><input type="checkbox"/> <b>Yes DVT: If yes, complete:</b> <input type="checkbox"/> Leg swelling <input type="checkbox"/> Calf Pain <input type="checkbox"/> Other _____</p> <p><input type="checkbox"/> <b>Yes PE: If yes, complete:</b> <input type="checkbox"/> Shortness of breath <input type="checkbox"/> Chest pain <input type="checkbox"/> Haemoptysis <input type="checkbox"/> Other _____</p>
<p>Diagnosis of VTE confirmed <input type="checkbox"/> <b>No</b></p> <p><input type="checkbox"/> <b>Yes If yes, complete:</b> <input type="checkbox"/> DVT <input type="checkbox"/> PE <input type="checkbox"/> DVT &amp; PE</p> <p style="text-align: center;"><b>(Please also complete the VTE form)</b></p>

<p>Did the patient receive LMWH i.e. all prescribed doses &amp; times</p> <p><input type="checkbox"/> <b>Yes</b></p> <p><input type="checkbox"/> <b>No If no, complete: How many doses missed</b> ___ out of ___ prescribed</p> <p style="text-align: center;"><b>Reason dose/s missed</b> _____</p> <p>If the patient remains in hospital post 1 week, please collect LMWH compliance for the entire admission.</p>
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<p><b>Were there any adverse events related to LMWH / GCS during the admission?</b> (If yes, please record on Adverse Events Form)</p>	<input type="checkbox"/> No	<input type="checkbox"/> Yes
<p><b>Were there any serious adverse events during the admission?</b> (If yes, please record on Serious Adverse Events Form)</p>	<input type="checkbox"/> No	<input type="checkbox"/> Yes

**FOLLOW-UP VISIT 2**  
**DUPLEX CLINIC VISIT (14 to 21 days post surgery)**  
**PLEASE FORWARD ANONMYSED DUPLEX REPORT TO TRIALS UNIT**

**ANONMYSED DUPLEX REPORT SENT TO TRIALS UNIT**  Yes  No If no, \_\_\_\_\_

Date of duplex report \_\_\_\_\_

**Right Leg**

Duplex Evidence of VTE  No

Yes If yes, complete location (tick all that are relevant):

- Below Knee (Calf / Distal popliteal)
  - Single calf vessel
  - >1 calf vessel
  - distal popliteal vein
- Above knee (Femoral / Proximal popliteal)
- Above the inguinal ligament (iliac vein)

(Please also complete the VTE form)

**Left Leg**

Duplex Evidence of VTE  No

Yes If yes, complete location (tick all that are relevant):

- Below Knee (Calf / Distal popliteal)
  - Single calf vessel
  - >1 calf vessel
  - distal popliteal vein
- Above knee (Femoral / Proximal popliteal)
- Above the inguinal ligament (iliac vein)

(Please also complete the VTE form)

<b>Were there any adverse events related to LMWH / GCS since discharge?</b> (If yes, please record on Adverse Events Form)	<input type="checkbox"/> No	<input type="checkbox"/> Yes
<b>Were there any serious adverse events since discharge?</b> (If yes, please record on Serious Adverse Events Form)	<input type="checkbox"/> No	<input type="checkbox"/> Yes
<b>What was the cost of patient travel?</b>	£____. ____ <input type="checkbox"/> not claimed	

## FOLLOW-UP VISIT 3 90 DAYS POST SURGERY

Date of Assessment: \_\_\_ / \_\_\_ / \_\_\_\_\_

(DD / MMM / YYYY)

Visit  In person  Over the telephone  From Hospital notes

Any VTE symptoms since the last visit / phone call:

None

Yes DVT: If yes, complete:  Leg swelling  Calf Pain  Other \_\_\_\_\_

Yes PE: If yes, complete:  Shortness of breath  Chest pain  Haemoptysis Other \_\_\_\_\_

Diagnosis of VTE confirmed  No

Yes If yes, complete:  DVT  PE  DVT & PE

(Please also complete the VTE form)

Were there any adverse events related to LMWH / GCS since follow-up 2? (If yes, please record on Adverse Events Form)

No

Yes

Were there any serious adverse events since follow-up 2? (If yes, please record on Serious Adverse Events Form)

No

Yes

## VTE FORM

Date VTE identified: \_\_\_ / \_\_\_ / \_\_\_\_\_

(DD / MMM / YYYY)

Imaging-confirmed Symptomatic DVT

Asymptomatic DVT identified by duplex

Imaging-confirmed symptomatic PE

Please forward a copy of the anonymised duplex report to the trials unit  Report sent

## ADVERSE EVENT FORM

<b>Adverse Event Description</b>	<p>Related to GCS:</p> <p><input type="checkbox"/> Discomfort</p> <p><input type="checkbox"/> Skin break / ulcer</p> <p><input type="checkbox"/> Skin necrosis,</p> <p><input type="checkbox"/> Skin Blistering</p> <p><input type="checkbox"/> Skin Rash</p> <p><input type="checkbox"/> Limb ischaemia</p> <p><input type="checkbox"/> Other AE of interest _____</p> <p>Related to LMWH (during admission or within 24 hours of discharge):</p> <p><input type="checkbox"/> Bleeding complication</p> <p><input type="checkbox"/> Rash / skin change tests</p> <p><input type="checkbox"/> Allergic reaction</p> <p><input type="checkbox"/> Thrombocytopenia,</p> <p><input type="checkbox"/> Abnormal liver enzyme</p> <p><input type="checkbox"/> Other AE of interest _____</p>
<b>Onset Date</b>	<p>___ / ___ / 20__</p> <p style="text-align: center;">(DD / MMM / YYYY)</p>
<b>Ongoing</b>	<p><input type="checkbox"/> Yes <span style="margin-left: 100px;"><input type="checkbox"/> No: end date ___ / ___ / 20__</span></p> <p style="text-align: right;">(DD / MMM / YYYY)</p>
<b>Treatment for AE</b>	<p>__ Please state _____</p>
<b>Outcome</b>	<p><input type="checkbox"/> Recovered</p> <p><input type="checkbox"/> Not yet recovered</p> <p><input type="checkbox"/> Unknown</p> <p><input type="checkbox"/> Fatal (please complete an SAE form)</p>
<b>AE Additional Details</b>	<p>Please state _____</p> <p>_____</p> <p>_____</p>



## SERIOUS ADVERSE EVENT FORM

<b>Serious Adverse Event Description</b>	<b>Please state</b> _____
<b>Serious reason</b>	<input type="checkbox"/> Death <span style="margin-left: 200px;"><input type="checkbox"/> Life threatening</span> <input type="checkbox"/> Persistently disabling <span style="margin-left: 100px;"><input type="checkbox"/> Hospitalisation required</span> <input type="checkbox"/> Congenital abnormality <span style="margin-left: 100px;"><input type="checkbox"/> Other medical important event: detail _____</span>
<b>Onset Date</b>	___ / ___ / 20 ___ (DD / MMM / YYYY)
<b>Treatment for SAE</b>	__ Please state _____
<b>Frequency</b>	<input type="checkbox"/> Single Episode <span style="margin-left: 100px;"><input type="checkbox"/> Intermittent</span> <span style="margin-left: 100px;"><input type="checkbox"/> Frequent</span> <input type="checkbox"/> Continuous <span style="margin-left: 100px;"><input type="checkbox"/> Unknown</span>
<b>Severity</b>	<input type="checkbox"/> Mild (aware of it easily tolerated) <input type="checkbox"/> Moderate (discomfort/interference with usual activity) <input type="checkbox"/> Severe (inability to carry out normal activity) <input type="checkbox"/> Life threatening or disabling
<b>Relationship to LMWH or GCS</b> <b>(LOCAL PI MUST ASSESS RELATIONSHIP)</b>	<input type="checkbox"/> <b>Not related</b> (no evidence of a causal relationship between LMWH / GCS and event). <input type="checkbox"/> <b>Unlikely</b> (there is little evidence (e.g. event did not occur within a reasonable time). There is another reasonable explanation for the event (e.g. clinical condition, concomitant treatment). <input type="checkbox"/> <b>Possible</b> (there is some evidence (e.g. event occurs within a reasonable time). However, there may be other factors (e.g. clinical condition, other concomitant treatments) <input type="checkbox"/> <b>Probable</b> (there is evidence to suggest a causal relationship. Other factors are unlikely. <input type="checkbox"/> <b>Definite</b> (there is clear evidence to suggest a causal relationship. Other factors can be ruled out)
<b>If Related, assess expectedness in relation to LMWH / GCS</b>	<input type="checkbox"/> Expected <span style="margin-left: 100px;"><input type="checkbox"/> Unexpected</span> <b>(PI MUST ASSESS EXPECTEDNESS)</b>
<b>Details of any intervention required / any further information</b>	<b>Please state</b> _____
<b>Ongoing</b>	<input type="checkbox"/> Yes <span style="margin-left: 100px;"><input type="checkbox"/> No: end date ___ / ___ / 20 ___</span> <span style="margin-left: 300px;">(DD / MMM / YYYY)</span>
<b>Outcome</b>	<input type="checkbox"/> Recovered <span style="margin-left: 100px;"><input type="checkbox"/> Not yet recovered</span> <input type="checkbox"/> Fatal <span style="margin-left: 100px;"><input type="checkbox"/> Unknown</span>

<b>Principal Investigator Signature (to confirm review and assessment of SAE)</b>	_PI SIGN_____DATE_____
---	------------------------

CI use only

<b>Does CI agree with the local PI assessment?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No (if not please complete below)
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<b>If no, CI relatedness</b>	<input type="checkbox"/> <b>Not related</b> (no evidence of a causal relationship between LMWH / GCS and event). <input type="checkbox"/> <b>Unlikely</b> (there is little evidence (e.g. event did not occur within a reasonable time). There is another reasonable explanation for the event (e.g. clinical condition, concomitant treatment). <input type="checkbox"/> <b>Possible</b> (there is some evidence (e.g. event occurs within a reasonable time). However, there may be other factors (e.g. clinical condition, other concomitant treatments) <input type="checkbox"/> <b>Probable</b> (there is evidence to suggest a causal relationship. Other factors are unlikely). <input type="checkbox"/> <b>Definite</b> (there is clear evidence to suggest a causal relationship. Other factors can be ruled out)
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<b>If Related, assess expectedness in relation to LMWH / GCS</b>	<input type="checkbox"/> Expected	<input type="checkbox"/> Unexpected
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## PROTOCOL DEVIATION FORM

<input type="checkbox"/> Patient randomised but surgery cancelled _____
<input type="checkbox"/> Patient Ineligible, if so please detail _____
<input type="checkbox"/> Patient withdrawn from trial intervention but continues to be followed –up, please state why _____
<input type="checkbox"/> Late Duplex, if yes, reason _____
<input type="checkbox"/> Missed Duplex, if yes, reason _____
<input type="checkbox"/> Late Visit, if yes, reason _____
<input type="checkbox"/> Missed Visit if yes, reason _____
<input type="checkbox"/> Patient randomised to ‘LMWH alone’ but wore stockings
<input type="checkbox"/> Patient randomised to ‘LMWH and stockings’ but did not wear stockings at all
<input type="checkbox"/> Flowtron use beyond theatre and recovery
<input type="checkbox"/> LMWH not given, unexpectedly discharged early
<input type="checkbox"/> LMWH not given, clinical decision
<input type="checkbox"/> LMWH not given, not prescribed
<input type="checkbox"/> LMWH not given, other reason (please detail)
<input type="checkbox"/> Other (please detail) _____ _____ _____

## CHANGE OF STATUS FORM

<p><b>Q1. Is this a post-randomisation exclusion?</b> (i.e. the participant was not eligible for the study)</p>	<p><input type="checkbox"/> <b>Yes, please state reason:</b></p> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <p><input type="checkbox"/> <b>No (Go to Q2)</b></p>
<p><b>Q2. Please provide change of status date:</b></p> <p style="text-align: center;">             ___ / ___ / 20___              (DD / MMM / YYYY)           </p>	
<p><b>Q3. Is this change of status as a result of:</b></p> <p><input type="checkbox"/> Death</p> <p><input type="checkbox"/> Loss to follow-up (patient cannot be contacted)</p> <p><input type="checkbox"/> Patient withdrawal:</p>	
<p><b>Q4. Who requested the change of status?</b></p> <p><input type="checkbox"/> Participant</p> <p><input type="checkbox"/> Clinician</p> <p><input type="checkbox"/> Other, please state _____</p>	
<p><b>Q5. Which of the following is the participant withdrawing from? (tick as many boxes as required)</b></p> <p><input type="checkbox"/> Trial treatment arm, please detail: _____</p> <p><input type="checkbox"/> Attending follow-up clinics</p> <p><input type="checkbox"/> Completing further questionnaires</p> <p><input type="checkbox"/> Relevant outcome data being collected via hospital and GP records (only complete if participant explicitly requests this)</p> <p><input type="checkbox"/> Contact from study office (telephone / email) excludes the posting of questionnaires *delete as appropriate</p>	



## Health Questionnaire

### English version for the UK

**The EQ-5D form must be completed at:**

**Please tick the relevant box to indicate:**

- Baseline**
- 1 week (or hospital discharge)**
- Between 14 to 21 days (at your scan)**
- At 90 days**

**Date of questionnaire completion:**    dd/mm/yy

Visit  In person  Over the telephone

Under each heading, please tick the ONE box that best describes your health TODAY.

### **Mobility**

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

### **Self-Care**

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

### **Usual Activities** (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

### **Pain/Discomfort**

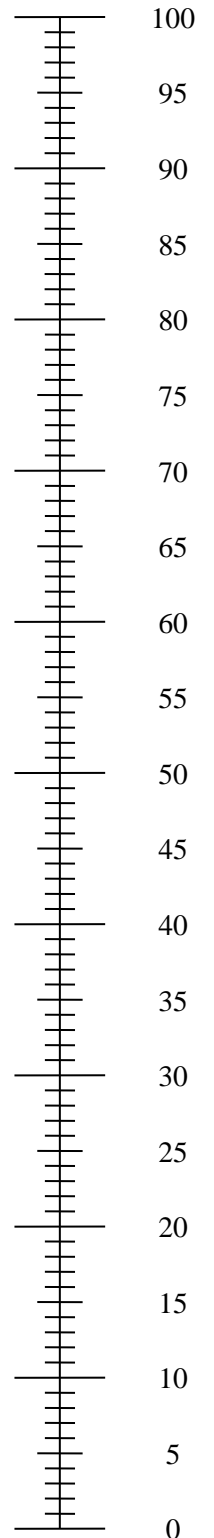
- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

### **Anxiety/Depression**

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.  
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health  
you can imagineThe worst health  
you can imagine



## Patient Diary

**\* To be completed by the patient \***

As part of the GAPS study we would like to collect information about any encounters with health professionals you may have had.

We hope that **you can complete this diary** every time you see a health professional to help us collect this information.

Please complete a section in this diary for **EVERY** time you **see or speak** to a health professional:

- Hospital appointments or admissions
- GP Clinic or Home Visits
- Telephone calls with a health professional
- Any scans or tests

SITE ID: \_\_\_\_\_

PATIENT ID: \_\_\_\_\_



PATIENT ID: \_\_\_\_\_

---

Please complete every section(s) below for each appointment or telephone conversation:

Date \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

1) Did you have any planned appointments from your doctor following your surgery:

- Yes (please state what e.g. routine follow-up) \_\_\_\_\_
- No

2) Reason(s) for seeing a medical professional:

- For your leg (s) please state reason \_\_\_\_\_
- Not for your leg (s) please state reason \_\_\_\_\_

3) Was this:

- An appointment
- Telephone conversation
- Home visit

4) Which health professional did you visit or speak to:

- Hospital Doctor
- Hospital Nurse
- GP
- GP Practice Nurse
- Other \_\_\_\_\_

5) Did you receive any advice or treatment (please complete as many as necessary):

- Medical advice: If so what \_\_\_\_\_
- Blood test (s)
- Scan (s): If so which part of your body \_\_\_\_\_
- Medication(s): If so what \_\_\_\_\_
- Other \_\_\_\_\_



**Stocking Compliance Diary**  
(Stocking Arm Only)

Date of operation: \_\_\_\_\_ Date of hospital discharge \_\_\_\_\_

Please complete this diary as honestly as you can.

It is important that we collect accurate information about when you wear your stockings.

We understand that you may not be able to wear your stockings all of the time.

Day	Date	Please tick to show when you wore your stockings				Estimated <b>number of hours</b> I wore my stockings in a day (total of 24 hours)	<b>Reason for not wearing stockings</b> , for example 'discomfort', 'inconvenience' 'forgot'
		I wore my stockings in the <b>morning</b>	I wore my stockings in the <b>afternoon</b>	I wore my stockings in the <b>evening</b>	I wore my stockings at <b>night (while sleeping)</b>		
1						____/24hrs	
2						____/24hrs	
3						____/24hrs	
4						____/24hrs	
5						____/24hrs	
6						____/24hrs	
7						____/24hrs	
8						____/24hrs	
9						____/24hrs	
10						____/24hrs	
11						____/24hrs	

**Graduated compression as an Adjunct to Pharmacoprophylaxis in Surgery (GAPS) Trial  
Stocking Compliance Diary**

*This project is funded by the National Institute for Health Research HTA (project number 14/140/61)*

Version 2.0

04/02/2016

(Approved by REC: London City Road & Hampstead NHS Research Ethics Committee on 08/02/2016)

12						____/24hrs	
13						____/24hrs	
14						____/24hrs	
15						____/24hrs	
16						____/24hrs	
17						____/24hrs	
18						____/24hrs	
19						____/24hrs	
20						____/24hrs	
21						____/24hrs	
22						____/24hrs	
23						____/24hrs	
24						____/24hrs	
25						____/24hrs	
26						____/24hrs	
27						____/24hrs	
28						____/24hrs	

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