CLOTS 3 - Randomisation Form

To randomise: WEB www.clotstrial.com OR PHONE XXX XXXX XXXX
Please ensure you have supplies of appropriate sleeves too!

CENTRE DETAILS

Country: _____ or code ☐☐

Centre name: _____ or code ☐☐☐

Responsible consultant: _____ or code ☐☐☐☐

Randomising person: _____

Has consent been given? ☐ **(Key 1)** **(must be yes)**

Patient' s Family name:_____ **Given name:**_____

Date of birth ☐☐/☐☐/ ☐☐☐☐ **(dd/mm/yyyy)** Sex: Male ☐ (Key 1) Female ☐ (Key 2)

Date of stroke onset ☐☐/☐☐/ ☐☐☐☐ **(dd/mm/yyyy)**

Date of admission ☐☐/☐☐/ ☐☐☐☐ **(dd/mm/yyyy)**

Yes **(Key 1)** No **(Key 0)** Unknown **(Key 9)**

1. Did the patient live alone before admission?	☐	☐	☐
2. Was the patient independent in everyday activities before this stroke? (i.e. walking, dressing, feeding, toileting & washing)	☐	☐	☐

The patient:

3. Is able to walk without the help of another person?	☐	☐
4. Is able to talk and orientated in time, place and person?	☐	☐
5. Is able to lift both their arms off the bed?	☐	☐
6. Is able to lift right leg off the bed?	☐	☐
7. Has a flicker of movement or better in the right leg?	☐	☐
8. Is able to lift left leg off the bed?	☐	☐
9. Has a flicker of movement or better in the left leg?	☐	☐
10. Is overweight?	☐	☐
11. Is known to be diabetic?	☐	☐
12. Is known to have symptoms or signs of peripheral vascular disease?	☐	☐
13. Is known to be a current smoker?	☐	☐
14. Is known to have a history of previous DVT or PE?	☐	☐
15. Has taken aspirin, dipyridamole (Persantin), or clopidogrel (Plavix) in last 24hrs?	☐	☐
16. Has been given rt-PA since admission?	☐	☐
17. Is on heparin or LMWH now?	☐	☐
18. Is on oral anticoagulants e.g. warfarin now?	☐	☐
19. Do you think it will be practical / possible to perform a second Doppler in 25 to 30 days time (in addition to one between Day 7 and 10)?	☐	☐

Treatment Allocation (please tick the appropriate box) **CLOTS Patient ID** _____

Apply intermittent compression sleeves ☐ **Avoid sleeves until discharge** ☐

- Sleeves, if allocated, should be worn whilst in bed or chair and until independently mobile or discharged home.
- Record the allocation on this form, in the medical notes and on the drug chart.
- Inform all the relevant people about the allocation then file this form in the patient's medical notes.
- Book the Doppler ultrasounds now so they will be done on Day 7-10 and Day 25-30.

Thank you for randomising this patient.

CLOTS 3 - Radiology Report Form

Enter online at www.clotstrial.com or return by fax XXX XXXX XXXX

Hospital Number: ☐☐☐ or Hospital Name: _____

Patient ID: _____ Patient Initials: _____ Date of Birth: _____ / _____ / _____

Procedure performed today Doppler ☐ Venography ☐ Both ☐

Date(s) procedure performed Doppler ____/____/____ Venography ____/____/____

Did this patient attend wearing compression sleeves? Yes ☐ No ☐

Results - Any D.V.T. present? Yes ☐ No ☐

If any DVT present please send best still picture that demonstrates this to the CLOTS Co-ordinating Centre (address below).

If Yes:

		Right Leg	Left Leg
Femoral:	Yes, definite	☐	☐
	Yes, probable	☐	☐
	None	☐	☐
Popliteal:	Yes, definite	☐	☐
	Yes, probable	☐	☐
	None	☐	☐
Calf:	Yes, definite	☐	☐
	Yes, probable	☐	☐
	None	☐	☐
	Veins Not Visualised/Examined	☐	☐

We need to know if you are aware of whether the patient has been wearing compression sleeves – this will tell us how "blind" you are to the treatment allocation

Do you think this patient has been wearing compression sleeves (Do not ask the patient!)?
Yes ☐ No ☐ No Idea ☐

Procedure performed by: Name of person doing scan _____
Radiologist ☐
Sonographer ☐
Technician ☐
Doctor ☐
Other – please specify _____

Name of person completing form _____Signature_____Date: ____/____/____
day month year

Enter online at www.clotstrial.com or return by fax XXX XXXX XXXX

CLOTS 3 - Discharge Form

Please complete this form on the patient's discharge from hospital, transfer from the centre or death (whichever occurs first) as accurately as possible.

Hospital Number OR Name: _____

Patient Identifiers: CLOTS ID: _____ Patient Initial: _____

ABOUT THE STROKE

Was stroke the final diagnosis in this patient? Yes ☐ No ☐
(a normal brain scan is compatible with a diagnosis of stroke)
If not a stroke, please specify the diagnosis:_____ ☐☐ For office use

Was the stroke due to: cerebral infarction? ☐ haemorrhage? ☐ uncertain?☐

DRUGS DURING HOSPITAL STAY

Has this patient taken any of the following drugs since randomisation (Tick all appropriate)?

Aspirin ☐ Dipyridamole (Persantin) ☐ Clopidogrel (Plavix) ☐ Other antiplatelet ☐

Prophylactic dose heparin/LMWH ☐ Treatment dose heparin /LMWH ☐

Warfarin ☐ Other oral anticoagulant ☐ **None**☐

If patient was given heparin, LMWH or warfarin during admission please give reasons:

To prevent stroke ☐
Artificial heart valve ☐
Atrial fibrillation (AF) ☐

To **prevent** DVT or PE ☐
To **treat** DVT or PE ☐

Other ☐ Please specify _____ ☐☐ For office use

Has the patient worn Graduated Compression Stockings during this admission? Yes ☐ No ☐

If yes, which length were worn? Long only ☐ Short only ☐ Both ☐

USE OF COMPRESSION SLEEVES

Since randomisation, has this patient

Worn thigh- length Compression Sleeves at any time? Yes ☐ No ☐

If **yes** on which leg(s)? Right ☐ Left ☐

If the allocated use of compression sleeves has not been followed, please give reasons below:

_____ ☐☐ For office use

If wore compression sleeves at any time since randomisation

Date sleeves first worn ___/____/____ Date sleeves last worn ____/____/____

Number of days (between these dates) sleeves **not** worn _____

If compression sleeves were taken off please tick one reason below:

Patient had 2nd Doppler after 30 days	☐	Patient refused to wear sleeves	☐
Patient completed 30 days of IPC	☐	Patient complained of discomfort	☐
Patient independently mobile	☐	Concerns about skin condition on legs	☐
Other difficulties encountered	☐	Please specify_____	☐☐

For office use

Please describe any skin problem on leg? _____ ☐☐

Did the skin problem resolve after removal of the IPC? _____ ☐☐

For office use

MAJOR EVENTS SINCE RANDOMISATION

Symptomatic or clinically apparent DVT?
(not clinically silent DVT diagnosed on screening Doppler)
Yes ☐ No ☐
If **yes** give date 1st diagnosed ___/___/___

Pulmonary Embolism?
Yes ☐ No ☐
If **yes** give date 1st diagnosed ___/___/___

Skin break on either leg?
(within 30 days of enrolment)
Yes ☐ No ☐
If **yes** give date 1st diagnosed ___/___/___

Fall resulting in injury?
(within 30 days of enrolment)
Yes ☐ No ☐
If **yes** give date 1st diagnosed ___/___/___

DETAILS ~ SYMPTOMATIC DVT

Were the symptoms of a DVT recognised before the Doppler ultrasound? Yes ☐ No ☐

If Symptomatic DVT diagnosed how was it confirmed?

Doppler ultrasound ☐ Venography ☐ Other ☐ Please Specify _____ ☐☐

For office use

Please specify the location(s) of any symptomatic DVT(s)

Right leg	Calf	☐	Popliteal	☐	Femoral ☐
Left leg	Calf	☐	Popliteal	☐	Femoral ☐

DETAILS ~ PULMONARY EMBOLISM

If Pulmonary embolism diagnosed how was this confirmed?

V/Q Scan ☐ CT Angiography ☐ Other ☐ Please Specify _____ ☐☐

For office use

DETAILS ~ SKIN BREAKS ON LEGS

Was patient wearing compression sleeves when developed skin break? Yes ☐ No ☐ Unsure ☐

Do you think the skin break was caused by the IPC sleeves or tubing Yes ☐ No ☐ Unsure ☐

Did the skin break heal before discharge? Yes ☐ No ☐ Unsure ☐

Did the skin break require any operative treatment (e.g. amputation) Yes ☐ No ☐ Unsure ☐

DETAILS ~FALLS RESULTING IN INJURY

Was the patient wearing compression sleeves at the time of the fall(s)? Yes ☐ No ☐ Unsure ☐

Do you think the fall was caused by the IPC sleeves or tubing? Yes ☐ No ☐ Unsure ☐

Did the patient sustain a fracture? Yes ☐ No ☐

Please provide details of injury due to fall below

_____ ☐☐

For office use

SURVIVAL & DISCHARGE

Did the patient survive to discharge from the randomising centre?

Yes ☐ No ☐

If **No, *date of death*** (dd/mm/yyyy) ____/____/___

Primary cause of death (please tick **one** box **only)**

☐ Neurological damage from initial stroke (e.g. coning) ☐ Pneumonia

☐ Pulmonary Embolism ☐ Recurrent stroke ☐ Coronary heart disease

☐ Other vascular, *please specify*:_____ ☐☐

☐ Non-vascular, *please specify* _____ ☐☐

☐ Due to compression sleeves, *please specify*:_____ ☐☐

☐ Uncertain, *please specify*: _____ ☐☐

For office use

Cause of death confirmed by autopsy? Yes ☐ No ☐

If **Yes, date of discharge** (dd/mm/yyyy)
____/____/____

Has the patient been discharged to: (tick **one** box **only**)

☐ Own home, alone ☐ At home, with partner or relative

☐ Relative's home ☐ Residential home

☐ Long term care/nursing home

☐ In hospital rehabilitation

☐ Other, *please specify* _____ ☐☐

For office use

Was this patient independently mobile on discharge? Yes ☐ No ☐

CONTACT DETAILS:

Patient's full postal address on discharge _____

Post Code: _____Telephone:_____

AND

Family Doctor's Name:_____

Full postal address:_____

Postcode:_____Telephone:_____

Please provide contact details of other persons (e.g. daughter or son) who does not live with patient:

Name: _____

Relationship:_____

Full postal address:_____

Postcode:_____Telephone:_____

AND ANOTHER

Name: _____

Relationship:_____

Full postal address:_____

Postcode:_____Telephone:_____

ADDITIONAL INFORMATION

(Please use this space below for any additional information you may think relevant to the trial or to the patient's treatment)

_____

☐☐
For office use

Name of person completing form _____

Signature _____

Date: ____/____/____
day month year

Enter online at www.clotstrial.com or fax back on **XXX XXXX XXXX**
CLOTS

CLOTS – 3 GP Questionnaire

Patients Name: <<Patient name >>

Date of Birth: << Date of Birth >>

Is this patient alive? ☐Yes ☐ No

If patient is still alive, please confirm that the following contact details are correct and amend if necessary

<< address >> <<Tel No.>>

Has the patient had any of the following since hospital discharge on <<date of discharge>>?

			If yes, what was the date first diagnosed?
Deep Vein Thrombosis?	Yes ☐	No ☐	__/__/___
Pulmonary Embolism?	Yes ☐	No ☐	__/__/___
Evidence of post-DVT leg syndrome? (i.e. swelling, pain, new ulcer)	Yes ☐	No ☐	__/__/___

If possible, please tell us how any of these diagnoses were confirmed (e.g. venography, VQ scan)

Is this patient taking warfarin? Yes ☐ No ☐

Reason why (in particular have they had a DVT or PE)

If this patient has died, please confirm the date and cause

Date of death __/__/___

Cause of death. _____☐☐

Was cause of death confirmed by autopsy? Yes ☐ No ☐

Name of person completing form _____Signature_____Date: ____/____/____
day month year

Thank you very much for your assistance.

Now please fax this form to us at XXX XXXX XXXX or send to:

The CLOTS Trial Co-ordinating Centre,

Bramwell Dott Building, Western General Hospital, Crewe Road, Edinburgh UK EH4 2XU

CLOTS - Follow-up Questionnaire

Dear <<patients name>> please answer the following questions:

Please tick one box on each line

	YES	NO
Has the stroke left you with any problems?	☐	☐
Do you need help **from anybody** with everyday activities?	☐	☐

How do you live now? *(please tick one box only)*

- On my own ☐
- With my partner or relatives ☐

Where do you live now? (*please tick one box only*)

- In my own home ☐
- In the home of a relative ☐
- In a residential home ☐
- In a nursing home ☐

YOUR TABLETS

Are you currently taking *(please tick appropriate boxes)?*

- Aspirin ☐
- Dipyridamole (Persantin) ☐
- Clopidogrel (Plavix) ☐
- Warfarin ☐

PROBLEM WITH YOUR LEGS?

YOUR RIGHT LEG

	Yes	No
Since discharge from hospital have you had a clot in this leg (deep vein thrombosis, DVT)?	☐	☐
Do you suffer from a swollen ankle or leg?	☐	☐
Have you had a leg ulcer since your stroke?	☐	☐

YOUR LEFT LEG

	Yes	No
Since discharge from hospital have you had a clot in this leg (deep vein thrombosis, DVT) ?	☐	☐
Do you suffer from a swollen ankle or leg?	☐	☐
Have you had a leg ulcer since your stroke?	☐	☐

YOUR LUNGS

	Yes	No
Since discharge from hospital, have you had a clot in your lungs (pulmonary embolus, PE)?	☐	☐

Tick ONE box next to the sentence which best describes your present state.

- [ ] I have no symptoms at all
- [ ] I have a few symptoms but these do not interfere with my everyday life
- [ ] I have symptoms which have caused some changes in my life but I am still able to look after myself
- [ ] I have symptoms which have significantly changed my life and I need some help in looking after myself
- [ ] I have quite severe symptoms which mean I need to have help from other people but I am not so bad as to need attention day and night
- [ ] I have major symptoms which severely handicap me and I need constant attention day and night

YOUR GENERAL HEALTH

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed/ chair ☐

Self-Care

I have no problems with self care ☐
I have some problems with washing or dressing myself ☐
I am unable to wash or dress myself ☐

Usual Activities

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

Pain/discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

Anxiety/depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

Did you complete this form yourself?

☐ Yes

☐ No, it was completed by a relative or friend

Date of form completion _____(day) _____ (month) ____(year)

We usually tell your GP how you are getting on based on your answers to our questions. Please tick this box if you would prefer us not to tell your GP ☐

Thank you very much for taking the time to complete this form

Please return it using the pre-paid envelope provided