

GUIDANCE ON PATIENTS MOVING SITES DURING CLOTS ACTIVITY

The ongoing reorganisation of stroke services in the UK, with some hospitals becoming a hyper acute unit and others focussing on acute and step down care means that some patients will move hospital during their CLOTS admission, either during or after the intervention phase (which lasts 30 days). To address research governance and confidentiality issues we suggest the following procedure should be adopted so that patients can move sites during the CLOTS trial and ensure the trial documentation and protocol are adhered to.

TRANSFERS WHERE RANDOMISING AND STEP DOWN UNITS ARE IN THE SAME TRUST

- The PI who has recruited the patient is responsible for their care in the trial.
- The PI has this role at both sites.
- Patients should remain in the trial, receive all 30 days of intervention and Dopplers between the protocol window of days 7-10 and days 25-30. (Remember we accept a Doppler later than the protocol window, but not earlier.)

TRANSFERS WHERE BOTH SITES ARE IN DIFFERENT TRUSTS

- The PI who has recruited the patient remains responsible for their care in the trial.
- Ensure there is approval for trial activity at the 2nd site. If this is a regular step down unit then it does make sense to have a copy of that approval and contacts on the delegation log at the two sites. (Remember the EU directive does not apply for CLOTS and we don't need to see the GCP certificates of those added to the delegation log.)
- If there is no approval in place it is still possible for the PI to request the Dopplers be undertaken when the clinical care is handed over, but this may or may not be practical or possible.
- If this is not possible, outstanding Dopplers will need to be arranged by the randomising centre once the patient is discharged.

TO TRANSFER A PATIENT ENSURE THE SECOND SITE IS IN A POSITION TO ACCEPT THE PATIENT

A courtesy email from the co-ordinator or Principal Investigator (PI) at the randomising centre to the PI or co-ordinator should alert the potential date of transfer of care and the requirement of a device at this unit and dates of due Dopplers. If a device requires to be transferred then this should remain with the patient during transfer and until day 30 (or the 2nd Doppler if later) and returned to the randomising centre after use.

DOCUMENTS

As soon as possible at transfer, the first (recruiting) centre should fax to the second centre:

- A copy of the consent form.
- A copy of the email summary outlining patient ID details, baseline data, allocated intervention and due dates of Doppler(s).
- Blank radiology report forms for the 1 or 2 Dopplers required.
- A part completed discharge form with contact details and initial diagnosis stroke type etc.
- Serial number of any device if sent with the patient.

The information that the patient is in the CLOTS trial **should** already be clearly documented in the notes, but should also be documented by the 2nd research team that the transfer information has been received and the current site notes now alert the staff and radiology to the fact the patient is in the study, the allocated intervention and the expected (and booked) dates of Dopplers.

SITE FILE

Your Trust may have a policy for dealing with patients recruited off site, but who are still receiving intervention or require investigations. We recommend you set up a separate file for correspondence and all documentation regarding this. If you regularly receive CLOTS patients you should make a file note in your own CLOTS site file to say this is happening. The randomising PI is responsible for ensuring the protocol is followed, adverse events are reported

etc so the PI should be happy that all correspondence and documentation associated with transferred patients is accessible as required.

Once the patient is discharged, or dies, or moves on from the 2nd site, the information in the discharge form can be faxed back to the original randomising centre.

Completed radiology reports (and scans if required) should be faxed back to the original randomising centre. This will ensure the PI and co-ordinator are in a position to have complete data for their patients and information to input back to the CLOTS centre themselves. There will of course be emails relating to the original transfer request email and further correspondence that will sit in the files for that patient so ensuring the whole journey whilst in the trial is documented, open and clear for all to see for audit and governance purposes.

TRANSFER TO NON CLOTS CENTRES

If a patient is transferred to a non CLOTS participating Trust, then that second centre will not be able to allow the devices to be used as they will not have Trust approval, received training in the devices or the protocol for the trial. Patients should, ideally, not be transferred to such a second site before the 7-10 day Doppler. Remember we are aiming to keep the devices on as long as possible.

If transfer is likely to happen before the 7 -10 day Doppler the patient should not be enrolled into the trial (since they will not receive the intervention with sufficient use to determine if the devices work).

If transfer is not expected before the first Doppler, but this happens clinically, the randomising centre should alert the new clinical team that the patient remains in the study and patient contact details should be provided to arrange for the due Dopplers, either at the 2nd site or by transferring them back to the randomising centre.

PATIENT GOES HOME

If a patient is discharged home from hospital before day 7 they should return for the 1st and 2nd Dopplers as an outpatient. We would also ask you to reflect that if you had anticipated this, should you have recruited the patient - again this early mobilising patient will provide little information about whether the devices work in immobile patients.

TRANSFER OF PUMPS

The devices are numbered and allocated to a centre. The whereabouts of the device is the responsibility of the randomising centre. If devices are moved, then this should be documented and the serial number information of the devices transferred (VO, or SO) should be noted.

The 2nd site should return the device to the randomising site once the 30 day period is up, or once the patient no longer wears the device.

If a second site e.g. a rehab ward is regularly receiving patients then training in the devices and the protocol should be provided. That site may need to keep its own pump sleeves and tubing for use. Contact the CLOTS Co-ordinating Centre to discuss.

MULTIPLE TRANSFERS

If a patient is transferred between many hospitals the above guidance should ensure the randomising centre can manage the data for patients they have recruited.

PAYMENTS

Doppler scans may be carried out by the second site, payment to be made via the randomising PI for this activity. This will need to be a local agreement as the PI receives the money for the data and the Dopplers for patients recruited at this site. Please note the CLOTS co-ordinating centre will not record which hospital carried out the Dopplers.

FOLLOW UP

All patients recruited into the study will remain in the trial and the CLOTS co-ordinating centre will undertake follow up as usual using the information from the discharge form.

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FOR RANDOMISING SITE

YOU ARE RESPONSIBLE FOR THE PATIENTS YOU RECRUIT INTO THE CLOTS TRIAL. YOUR COMMITMENT TO THEM INCLUDES:

- complying with the protocol
- arranging the Dopplers to investigate if they have developed a deep vein thrombosis
- to provide the data to the CLOTS co-ordinating centre in Edinburgh
- complying with the research governance framework within your Trust

IF YOU NEED TO TRANSFER A PATIENT WITHIN YOUR TRUST, PLEASE ENSURE THE SECOND SITE IS IN A POSITION TO ACCEPT THE PATIENT

- Send a courtesy email to the PI or co-ordinator at the 2nd unit to alert the potential date of transfer of care, the requirement of a device at this unit and dates of due Dopplers. Find out their fax number.
- Determine if a device is free at the 2nd unit if required. If so, ensure the numbered device remains with the patient as they are transferred. Check extra sleeves are also in place for this patient - if not, send spares over.
- Enquire about availability of Dopplers on due dates, and confirm the 2nd site has ability to arrange this Doppler.

DOCUMENTS

You will have already documented the patient's capacity, inclusion into the study, intervention and Doppler due dates in their notes. As soon as possible at transfer, you should fax to the second centre:

- A copy of the consent form.
- A copy of the email summary outlining patient ID details, baseline data, allocated intervention and due dates of Dopplers. This document is available as an email to print off at randomisation or contact the CLOTS co-ordinating centre for a copy.
- Radiology report forms for the 1 or 2 Dopplers as required.
- A part completed discharge form with next of kin contact details, initial diagnosis, stroke type, medication given so far etc.
- Serial number of the device if transferring.
- Your contact details to report any SAE to the randomising PI.

SITE FILE

- Note in your patient file the transfer of the patient, the serial number of device they have with them and contact at 2nd site.
- Keep the original contact email alerting the 2nd site and their response as significant correspondence for this patient.

DATA

- Return completed radiology reports on line or return by fax to the CLOTS co-ordinating centre.
- Once the patient has died or is discharged, the further completed discharge form should be faxed back to you. Clarify any local queries.
- Complete discharge form on line.

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FOR STEP DOWN SITE

FIRST CONTACT

If you receive a contact email do consider if you have:

- Devices to spare (if required)
- Sleeves of the correct size
- A Doppler slot available on the required dates

You should alert the ward staff to the imminent arrival of a trial patient.

DOCUMENTS

The randomising centre should fax you:

- A copy of the consent form.
- A copy of the email summary outlining patient id details, baseline data, allocated intervention and due dates of Doppler.
- Radiology report forms for the 1 or 2 Dopplers required.
- A part completed discharge form with contact details and initial diagnosis stroke type medication given so far etc.
- Serial number of the device if transferring.
- Their contact details to report any SAE to the randomising PI.

You should keep this information in a file set aside for patients not recruited at this site.

DELIVERY OF THE PATIENT

Once the patient is with you:

- Make sure the patient is OK and introduce yourself.
- Ensure the sleeves and pump are working.
- Apply 'stickies' to drug sheet so ward staff can record the device wearing at the drug round.
- Complete Doppler requests according to local requirements.
- Document in the notes dates of due Dopplers and in the ward diary to ensure staff remove sleeves prior to the Doppler.

DEVICES

If the patient no longer requires the device please clean, and if on loan, return this to the randomising centre.

DOPPLER

Once the Doppler(s) are complete please fax the radiology report to the randomising centre. Any positive DVT image will also need to be sent to the randomising centre.

DISCHARGE

Once the patient is discharged from your care, or dies at your centre please complete the discharge form annotating the information as required. Please fax this to the randomising centre.

If a Doppler is still due please alert the randomising centre to the patients whereabouts so they can arrange the Doppler.