



www.so2s.co.uk

SOS - Spring 2013

May 2013

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Top 10 centres

Uni. Hosp. North Staffs.	470
St George's	281
Royal Liverpool	251
Royal Bournemouth	234
King's College	225
Leeds Teaching	192
Southend	187
Salford Royal	185
Countess of Chester	174
Royal Victoria Inf.	160

Only 222 randomisations to go!

Thanks to all of your hard work, at the time of writing this newsletter, we only have 222 patients to randomise before we hit our target of 8000.

When we reach 8000

Once the 8000th patient has been randomised we will put an announcement on the website homepage and send an e-mail out to all research sites.

What if I've started randomizing a patient and we've reached 8000?

Don't worry, if you have taken consent for the pa-

tient to participate in the study then carry on randomising the patient. The online randomisation wizard will be disabled from the end of the day to allow all patients that have consented to take part in the trial.

Close out

We are going to use a remote close-out procedure as we will not be able to visit all 136 sites that are open for recruitment to SOS. In the next few months you will receive a CD, in the post, with clear instructions on how to complete the close-out

process and all documentation required for the investigator site file (ISF) to be updated prior to archiving.

12 month Follow-up

Please do not forget that randomised patients will be followed-up for 12 months and we will still need the randomising centre to carry out safety reporting procedures and help us with readmission, GP contact details and notifications of death. There may also be data queries generated once the database has been locked and we will be in contact with individual sites about these.

Amendments...

We have changed the wording on the consent form, created a new independent physician consent form, added a discharge form to the CRF and added a question about patients' sight to the 3, 6 and 12 month follow-up questionnaires. An e-mail has been sent to all recruiting centres with an amendment receipt and

acknowledgement form, the REC and MHRA approval letters, and the substantial amendment notification form. The receipt form is to be signed by the PI and sent back to the coordinating centre along with the R&D approval letter for the amendment. If the PI is currently unavailable a co-investigator with suitable delegated

responsibilities on the delegation log can sign the form. We then ask for the PI to sign the form on their return. If you have any questions about this process please contact Tracy or Alison at the coordinating centre on 0300 123 0891.

Further information and the new forms to be downloaded are available on the SOS website (www.so2s.co.uk).

Patient wishes to withdraw from SOS

When a patient wishes to withdraw from the Stroke Oxygen Study please find out whether the patient wishes to:

1. withdraw from the trial completely, including follow-up
2. withdraw from receiving treatment but is happy for us to use the data collected so far or,
3. withdraw from receiving treatment but is happy to receive the follow-up questionnaires.

When a patient withdraws from the study please complete the 'Patient event data' form on the online SOS database and give as much information as to the reason for the withdraw.

Please do not withdraw a patient from SOS on the basis of a final diagnosis that is not stroke. For example, if a patient has had a migraine the patient still remains in the trial and all treatment (if relevant), week-1 assessments and follow-ups are still required.

SAEs and follow-ups

- Safety reporting remains the responsibility of the randomising site even if the patient is repatriated to a different site.
- The PI must review and sign all SAEs. It is acceptable for a co-investigator who has been delegated the responsibility of completing SAEs (in accordance with the delegation log) to carry out this task.
- If all questions A-F on the front page of the SAE form are answered 'no' then it is an AE not a SAE and the AE form is to be completed and faxed to the Sponsor only. It is down to the PI at the research site to decide the answers to these questions.
- Please ensure that a SAE category (section C of SAE form) is completed by the PI.
- If you are sending a follow-up to a previously submitted SAE form please mark it clearly as 'follow-up' so we know not to start processing it as a new event.

Invoicing for randomised patients.

Please note that the address to send invoices for SOS to has changed. Please send the invoices to the following address:

FAO - Dr Tracy Nevatte
Stroke Oxygen Study
North Staffordshire Combined Healthcare NHS Trust
Holly Lodge
62 Queens Road
Stoke on Trent
ST4 7LH



If you forget your log-in details for the online database please follow the 'forgotten my password' link on the log-in page and your details will be e-mailed to you.