Stroke Oxygen Study Newsletter

Summer 2012

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Top 10 centres

Uni. Hosp. North Staffs.	418
St George's	231
Royal Bournemouth	214
Royal Liverpool	207
King's College	189
Southend	182
Salford Royal	159
Leeds Teaching	157
Countess of Chester	152
Musgrove Park	146

Update from the Study Centre

August 2011to August 2012 has been a busy year for the SO2S study all round.

Funding

NIHR Health Technology Assessment programme funded project

It saw us complete our NIHR Research for Patient benefit (RfPB) funded part of the study in August 2011 and the start of our NIHR HTA funded part.

The HTA funding will allow us to recruit the 6,600 participants we are looking for in order to answer or research questions. This funding started on the 1st September 2011 and is until the 30th June 2015.

The study continues to be a joint research project between the ISTM, Keele University and North Staffordshire Combined Healthcare NHS Trust.

Participant Recruitment

For the year **2011/2012** **2,601** participants were randomized into the trial. This meant our total recruitment up to the end of August 2012 was **6,345**. This has exceeded even our revised targets we proposed for the NIHR HTA funding. This recruitment is from our 123 centers' . Many thanks for all your hard work.

North Staffordshire Combined Healthcare NHS Trust
A Keele University Teaching Trust

INSTITUTE FOR SCIENCE AND TECHNOLOGY IN MEDICINE

Keele University

Staff changes...

Study Manager

Dr Sarah Pountain has left the Stroke Oxygen Stud- for a new role in Birmingham and we wish her well for her future. Dr Tracy Nevatte has replaced Sarah as study manager and she looks forward to working with everyone.

Coordinating Centre

Our team at the coordinating centre has grown with our new funding.

Many of you may have already met Alison Buttery, our Data Manager. We also have some new Data Assistants: Joy Dale, Wendy Lawton and Nicola Mellor. Joy, Wendy and Nicola are involved with the follow-up questionnaires; sending them out, data entry and any queries which are generated from this.

With on average approx 140 patients recruited a month, you can imagine the workload for the 3, 6 and 12 month follow up questionnaires to be sent out on time. There are also all the follow-ups for those patients who have not returned their questionnaires and for all the data to be entered. They are certainly kept busy!

SAEs

Can we remind centres that any adverse events which are classed as serious and occur within the 12 months from randomization, will require an SAE form to be completed.

If you can complete the SAE with as much information as possible initially, if you have limited details you can report what you know and then send through the follow up information as soon as you obtain it.

All SAEs should be completed on the SAE form, included in the CRF, and faxed to the coordinating centre (0300 123 0894) AND to our Sponsor (01782 441624) within 24 hours of you becoming aware of the event. Please note, we are not using the online system for submitting SAEs.

If the adverse event is not classed as serious AND the cause is possible, probably or defiantly related to the IMP (oxygen in this study) or the cause is unknown then this will need to be reported to our Sponsor as an AE.

The AE report forms can be found on our website on the procedures page. These should be faxed to our Sponsor (01782 441624) within 14 days of you becoming aware of the event.

If you have any queries, questions or need advice please contact the coordinating centre.

Please ensure all SAEs are faxed to us at the coordinating centre and to our Sponsor. We do not use the online system for SAEs.

Consent Process

Regarding obtaining consent for the study if a patient lacks capacity to provide their consent then written consent can be sought on the patients behalf from a relative, carer, legal representative or independent physician (subject to local policy).

The relative, carer or legal representative consent form should be used, as well as the relative, carer or legal representative information sheet. It should be clearly documented in the patients notes that at the time the patient was reviewed and lacked capacity to provide consent and to whom consent was obtained on behalf of the patient.

At randomization on the paper and electronic case record form it should be documented whether it was the patient or relative/carer/legal representative who provided consent. Please ensure this question "has the patient given fully informed consent?" on the eCRF is answered correctly. If the relative has given consent then this is NOT the patient.

If the patient subsequently regains capacity then fully informed patient consent should be obtained as soon as the patient is able to do so. This will be documented on the week one follow-up form.

Please make sure you file the original consent form in the patients' medical notes.

Data Queries

It is paramount that we collect data of the highest quality to analyse and allow us to answer our research questions. We do appreciate all your efforts in randomizing patients, collecting and entering the follow up data.

There are times however when we have queries regarding data and we may contact you to clarify things. Some of the common queries we have are:

Missing data with no explanation. If a patient has been discharged, therefore observations are not available please state this in the notes section on the eCRF and leave the data entry field blank.

If observations have been missed, then leave the data entry field blank—please state the explanation for this in the notes section of the eCRF and discuss why this has occurred with the ward staff.

We all strive to ensure a complete data set is obtained, but when this has not occurred a valid reason needs to be provided and if necessary the reason highlighted to the relevant people to ensure it does not occur again (e.g. with missing observations/ oxygen compliance not documented).

As you can appreciate this will ensure we have data of the highest quality.

Monitoring Visits

Many of our centres will have received a monitoring visit in the last couple of months.

I hope the centres have found this a useful experience, from our side it is nice to be able to re-visit centres and see how they are getting on.

One issue that has arisen regards inaccuracies between observation readings for the highest/lowest oxygen saturation, temperate, heart rate and blood pressure. We ask that you take the time to ensure you accurately read the data from the observation charts and that it is for the intervention period.

With so many centres we are still working our way around you all. If you would like a monitoring visit please contact the coordinating centre and we can incorporate this into our programme.

A multi-centre, prospective, randomised, open, blinded-endpoint study to assess whether routine oxygen treatment in the first 72 hours after a stroke improves long-term outcome

The SOS study is funded by the National Institute for Health Research - research for Patient Benefit and is a portfolio study adopted by the Stroke Research Network

WWW.SO2S.CO.UK

BCTU Online System

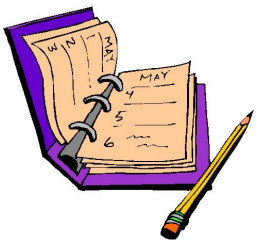
For new researchers who require a username for the online data entry system you must provide the following documents:

- Signed research CV
- Current GCP certificate (dated within the last 2 years)
- Copy of the delegation log with them included and signed by the PI.

These can be faxed to us (0300 123 0894) or e-mailed to the study manager.

Once we have these we will then request a username to be set-up. This new researcher will receive an e-mail from the BCTU with a link to activate their username.

If you forget your password please follow the link on the log-in screen.



Notification of Death

When a SO2S participant dies it is important for the notification of death to be completed online. A cause of death is required for every patient in the trial who dies. Also, a paper SAE must be faxed to the coordinating centre and Sponsor, not completed online.

If you need any help with this please contact the study manager (03001230891).

Contact the study coordinating centre if you would like to arrange a monitoring visit.

Dates for the Diary

22nd European Stroke Conference

22nd—25th May 2013

London

UK Stroke Forum

4th—6th December 2012

Harrogate

Recruitment by Study Centre (up to 31st August 2012)

Centre	Total randomised	Centre	Total randomised
Addenbrooke's Hospital	6	North Tyneside	67
Airedale General Hospital	23	Northwick Park	48
Altnagelvin Hospital	4	Nottingham	5
Antrim Area Hospital	12	Pennine Acute Trust	118
Arrowe Park	1	Peterborough	14
Barnsley	66	Pilgrim Hospital	24
Basildon	4	Pinderfields	11
Basingstoke	5	Poole General Hospital	21
Bedford	2	Princess Alexandra, Harlow	9
Birmingham Heartlands	122	Princess Royal, Telford	47
Bishop Auckland	35	Queen Alexandra Portsmouth	28
Blackpool Victoria	71	Queens Burton	119
Bradford	29	Rotherham District General	41
Brighton & Sussex	128	Royal Albert Edward, Wigan	13
Bronglais	0	Royal Blackburn	36
Broomfield	4	Royal Bournemouth	214
Calderdale	12	Royal Cornwall	102
Charing cross	76	Royal Derby	33
City Hospital, Birmingham	10	Royal Hallamshire	6
Colchester Hospital	26	Royal Hampshire	2
Countess of Chester	152	Royal Lancaster	15
Craigavon Area Hospital	15	Royal Liverpool	207
Darrent Valley	1	Royal Preston	135
Derriford	73	Royal Surrey	23
Devon & Exeter	103	Royal United, Bath	91
Doncaster & Bassetlaw	27	Russells Hall, Dudley	3
Dorset County Hospital	27	Salford Royal	159
East Kent - QE Queen Mother	76	Salisbury	3
East Surrey	25	Scarborough	3
Eastbourne	55	Solihull	36
Erne Hospital	1	South Tyneside Hospital	11
Freeman & Royal Victoria	145	Southampton	18
Frenchay Hospital	20	Southend Hospital	182
Frimley Park	13	Southport & Formby	39
Gloucestershire	12	St George's	233
Good Hope	10	St Helen's & Knowsley	82
Harrogate District Hospital	18	St Peter's	36
Hereford Hospital	7	St Richard's	0
Hexham	4	Stepping Hill	58
Hull	4	Sunderland	56
Ipswich Hospital	6	Torbay	71
James Cook	53	Trafford General Hospital	8
James Paget Hospital	1	Ulster Hospital	19
Kent & Canterbury	60	Uni. College Hosp. London	29
Kettering General	9	Uni. Hosp. Aintree	126
Kings College	189	Uni. Hosp. Birmingham	61
Kings Mill	6	Uni. Hosp. Bristol	127
Kingston	0	Uni. Hosp. Leicester	49
Leeds Teaching Hospital	157	Uni. Hosp. Lewisham	1
Leighton Hospital	82	Uni. Hosp. North Durham	82
Lincoln	0	Uni. Hosp. North Staffs.	418
Luton & Dunstable	37	Uni. Hosp. Princess Royal (Orpington)	24
Macclesfield General	48	Walsgrave Hospital	116
Manchester Royal Infirmary	4	Wansbeck	99
Manor Hospital, Walsall	40	Warrington Hospital	69
Mayday Hospital (Croydon Uni Hosp.)	3	Warwick	10
Medway	29	Watford Hospital	12
Mid Staffs	0	West Cumberland	26
Morriston	0	West Suffolk	10
Musgrove Park	146	Whipps Cross	0
Neville Hall Hospital	9	William Harvey	41
New Cross	72	Wycombe General	12
Norfolk & Norwich	33	Wythenshawe	5
Northampton	50	Yeovil	21
North Devon	36	York	75
North Middlesex	0		