

NRES Committee West Midlands - Staffordshire

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18 October 2012

Dr Tracy Nevatte
SOS Study Manager
National Institute for Health Research
Stroke Oxygen Supplementation Study
North Staffs Combined Healthcare NHS Trust
Holly Lodge, 62 Queen's Road
Stoke-on-Trent, ST4 7LH

Dear Dr Nevatte,

Study title:	The Stroke Oxygen Study. A randomised controlled study of the benefits and risks of routine oxygen treatment after acute stroke
REC reference:	06/Q2604/109
Protocol version:	2
EudraCT number:	2006-003479-11
Amendment number:	Sponsor's protocol amendment number 6 REC amendment number 16
Amendment date:	04 October 2012

- The amendment proposes to increase the number of participants by 1400 to 8000.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The committee asked for the following clarifications –

Is the study is a pilot study?

Why is there a need for such a large number of participants?

How long is the study likely to take?

You clarified that the study is no longer a pilot study. The protocol used for the main study (the current one) is the same as that developed for the pilot study. The need for the large number of patients is because currently, looking at randomisation data, you do not have as many 'moderate to severe' NIHSS classified strokes as originally envisaged; this may adversely affect the power of the trial. Increasing the recruitment target will raise the power for the 'moderate through to very severe' strokes subgroup from 43% to 50%. recruitment was originally due to end January 2014 (target 6600) however, you reached this target earlier this month. Funding is secured until June 2015. With the new target, recruitment will end May 2013, as the average of recruitment is 200 patients per month.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation and the further clarifications.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter		04 October 2012
European Commission Notification of Substantial Amendment Form		04 October 2012
Protocol	Version 2, Amendment 6	03 October 2012
Email from Dr T Nevatte with further information		17 October 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

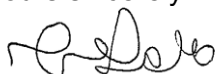
This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q2604/109:	Please quote this number on all correspondence
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Yours sincerely



Signed on behalf of:
Dr Kathryn Kinmond
Chair

E-mail: nrescommittee.westmidlands-staffordshire@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Laurie Wrench - North Staffordshire, Harplands Hospital
Professor Christine Roffe - North Staffordshire Combined Healthcare NHS Trust

NRES Committee West Midlands - Staffordshire

Members of the Sub-Committee

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mrs Shirley Ann Goldstraw	Lecturer in Midwifery	Expert
Dr Kathryn Kinmond (Chair)	Senior Lecturer	Lay Plus