

National Research Ethics Service

Wandsworth Research Ethics Committee

South London REC Office (1)
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St Georges University of London
Cranmer Terrace
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SW17 0RE

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Date: 1st March 2010

Professor Hugh Markus
Professor of Neurology, St George's, University of London
Centre for Clinical Neuroscience, Division of Cardiac and Vascular Sciences
Room 0.124, Ground Floor Jenner Wing
Cranmer Terrace,
London SW17 0RE

Dear Professor Markus

Study title: Feasibility of a therapeutic trial in patients with cervical arterial dissection
REC reference: 04/Q0803/215
Protocol number:
EudraCT number: NA
Amendment number: 15
Amendment date: 13 November 2009

The above amendment was reviewed on the 22nd February 2010 by the Sub-Committee in correspondence.

Ethical opinion

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.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Standard operating procedure chart	2	24 th September 2009
CADISS medication		
CADISS discharge letter	1	24 th September 2009
European Commission Notification of Substantial Amendment Form	15	13 th November 2009
Covering Letter		4 th November 2009
Patient contact letter	1	19 th January 2010
GP contact letter	1	19 th January 2010
PCT contact letter	1	19 th January 2010

Patient confirmation of consent form (after recovery)	1	19 th January 2010
Relative/carer assent form	1.1	19 th January 2010
Participant Consent Form: Witnessed consent form	1.1	19 th January 2010
Participant Consent Form	5.1	19 th January 2010
Participant Information Sheet: for relatives and carers	1.1	19 th January 2010
Participant Information Sheet	6.1	19 th January 2010
Protocol	8.1	19 th January 2010
Correspondence letter		15 th January 2010

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.

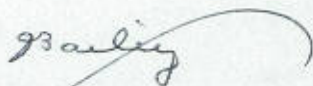
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

04/Q0803/215:

Please quote this number on all correspondence

Yours sincerely



Ms Joan Bailey
Committee Co-ordinator

E-mail: lsbrec@stgeorges.nhs.uk

Enclosures:

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

Copy to:

Prof David Oliveria, St Georges Hospital Medical School

Ms Zuhur Balayah
St George's Joint Research Office
Ground Floor, Hunter Wing
St. George's University of London
Cranmer Terrace
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SW17 0RE

Wandsworth Research Ethics Committee

Attendance at Sub-Committee of the REC Meeting held on the 22nd February 2010

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Christine Heron	Consultant Radiologist	Expert
Professor George Hall	Professor of Anaesthesia	Expert

Written comments received from:

<i>Name</i>	<i>Position</i>
Dr Christine Heron	Consultant Radiologist
Professor George Hall	Professor of Anaesthesia