



Health Research Authority

NRES Committee London - South East

Bristol Research Ethics Committee Centre
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22 April 2014

Mr Paul Cartledge
Research Innovation Services, University of Nottingham
Kings Meadow Campus, Lenton Lane
Nottingham NG7 2NR

Dear Mr Cartledge

Study title: Safety and tolerability of clopidogrel when added to aspirin and dipyridamole in high risk patients with recent ischaemic stroke: a randomised controlled trial

REC reference: 08/H1102/112

Protocol number: 31350

EudraCT number: 2007-006749-42

Amendment number: SA 03/14

Amendment date: 14 March 2014

The above amendment was reviewed 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
SA0314 Changes doc		
Protocol	1.5 (clean & tracked)	28 February 2014
European Commission Notification of Substantial Amendment Form	SA 03/14	14 March 2014

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.

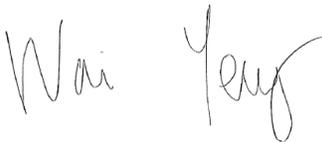
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

08/H1102/112:**Please quote this number on all correspondence**

Yours sincerely



Mr Wai Yeung
Research Ethics Committee (REC) Assistant

pp Professor David Caplin
Chair

E-mail: nrescommittee.london-southeast@nhs.net

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

Copy to: Professor Philip M. W. Bath, University of Nottingham

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Attendance at Sub-Committee of the REC meeting

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Professor David Caplin	Physicist	Lay
Professor John Eastwood	Consultant Renal Physician	Expert

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Rajat Khullar	REC Manager