

NRES Committee London - South East

Bristol Research Ethics Committee Centre
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10 February 2014

Professor Philip M. W. Bath
Professor of Stroke Medicine
University of Nottingham
Division of Stroke Medicine - Research Dept
Clinical Sciences Building
City Hospital Campus
Hucknall Road
Nottingham NG5 1PB

Dear Professor Bath

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:	Substantial Amendment
Amendment date:	31 January 2014

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

Ethical opinion

None.

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
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European Commission Notification of Substantial Amendment Form	Substantial Amendment	31 January 2014
Covering Letter		31 January 2014
GP/Consultant Information Sheets		
Tardis GP letter Information for General Practitioners at Baseline	1.0	23 January 2014
Day 35		
Day 90	1.3	23 January 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.

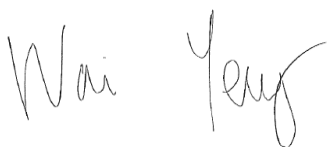
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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: Mr Paul Cartledge

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Attendance at Sub-Committee of the REC

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Professor David Caplin	Physicist	Lay
Mr Ron Driver	University Lecturer/Statistician	Lay
Professor John Eastwood	Consultant Renal Physician	Expert

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Rajat Khullar	Committee Coordinator