



Health Research Authority

London - South East Research Ethics Committee

Barlow House
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4 Minshull Street
Manchester
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01 April 2016

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: SA03/16

Amendment date: 23 March 2016

IRAS project ID:

The Substantial Amendment proposed to put the trial on hold and temporarily halt randomisation on the recommendation of the Data Monitoring Committee for safety reasons.

The above amendment was reviewed on 01 April 2016 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		22 March 2016
Notice of Substantial Amendment (CTIMP)	SA03/16	23 March 2016

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
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Yours sincerely

PP 

**On behalf of 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

London - South East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 01 April 2016

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor David Caplin	Physicist	Yes	
Mr Guy Gardener	Retired Assistant Chief Constable	Yes	
Ms Vanda Taylor	Senior Cancer Information Nurse	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Katie Southeard	REC Assistant