



Health Research Authority

London - South East Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

30 March 2016

Diane Havard
Senior Clinical Trials Manager
Stroke Division of Clinical Neuroscience
School of Medicine
Faculty of Medicine and Health Sciences
Room A29, Clinical Sciences Building
University of Nottingham
City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

Dear Diane Havard

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 proposes to put the trial on hold and temporarily halt randomisation on the recommendation of the Data Monitoring Committee for safety reasons.

Thank you for submitting the above amendment, which was received on 30 March 2016. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

<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

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

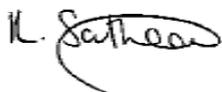
All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

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



Katie Southeard
REC Assistant

Email: nrescommittee.london-southeast@nhs.net

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