



National Research Ethics Service

South East Research Ethics Committee

South East Coast Strategic Health Authority
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21 October 2010

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 number: 08/H1102/112

Protocol number: 31350

EudraCT number: 2007-006749-42

Amendment number: SA04/10 31 August 2010 New Sites and change PI at existing sites

Amendment date: 31 August 2010

Thank you for submitting the above amendment, which was received on 20 October 2010.

Research Site	Principal Investigator / Local Collaborator
Colchester Hospital University NHS Foundation Trust, Colchester General Hospital, Turner Road, Colchester CO4 5JL	Ramachandran Sivakumar
Mosely Hall Hospital, 181 Alcester Road, Birmingham B13 8JL	Don Sims
North Bristol NHS Trust, Frenchay Day Hospital, Frenchay Park Road, Bristol BS16 1LE	Neil Baldwin
The Mid Yorkshire Hospitals NHS Trust (covering: Dewsbury & District Hospital and Pinderfields General Hospital)	Prabal Datta
Basildon & Thurrock University Hospitals NHS Trust, Basildon University Hospital, Nethermayne, Basildon, Essex SS16 5NL	Farhad Huwez
Plymouth Teaching PCT, Stroke Unit, Mount Gould Hospital, Mount Gould Road, Plymouth PL4 7QD	Elizabeth Househam

The amendment relates solely to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. The

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site-specific assessment for the site(s) will therefore form part of the research governance review. The Site-Specific Information (SSI) Form for the site should be included with the application for R&D approval.

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant NHS/HSC R&D office(s) prior to the study starting at the site.

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.

08/H1102/112

Please quote this number on all correspondence

Yours sincerely



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Committee Co-ordinator

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Copy to: *Professor Philip M. W. Bath, University of Nottingham*
Margaret Adrian, TARDIS TRIAL Nurse Co-ordinator