



National Research Ethics Service

South East Research Ethics Committee

South East Coast Strategic Health Authority

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29 October 2009

Mr Paul Cartledge
Research Innovation Services,
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Kings Meadow Campus, Lenton Lane
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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: 1.1

EudraCT number: 2007-006749-42

Amendment number: SA02/09

Amendment date: 28 October 2009

Thank you for submitting the above amendment, which was received on 28 October 2009.

Research Site	PI / Local Collaborator
James Paget University Hospitals NHS Foundation, Lowestoft Road, Gorleston, Great Yarmouth, Norfolk, NR31 6LA	Peter Harrison
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Countess of Chester NHS Foundation Trust, Liverpool Road, Chester, CH2 1UL	Kausik Chatterjee
The Royal Liverpool & Broadgreen University Hospital NHS Trust, Royal Liverpool Hospital, Prescott St, Liverpool, L7 8XP	Aravind Manoj

This Research Ethics Committee is an advisory committee to South East Coast Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Stroke Team for Audit and Research (STAR), Dept for Medicine for the Elderly, University Hospital Aintree, Liverpool, L9 7AL	Raj Kumar
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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 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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Copy to: *Margaret Adrian, Nottingham University Hospitals NHS Trust*