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# National Research Ethics Service

South East Research Ethics Committee

South East Coast Strategic Health Authority

Preston Hall

Aylesford

Kent

ME20 7NJ

Telephone: 01622 713048

Facsimile: 01622 885966

29 September 2009

Margaret Adrian  
TARDIS Trial – Nurse Coordinator  
Nottingham University Hospitals NHS Trust  
Division of Stroke Medicine  
City Hospital Campus  
Clinical Sciences Building  
Hucknall Road  
Nottingham NG5 1PB

Dear Ms Adrian

**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:**

**Amendment date:** 03 September 2009

Thank you for submitting the above amendment, which was received on 10 September 2009.

Research Site	Principal Investigator / Local Collaborator
Norfolk & Norwich University Hospital NHS Trust, Olney Lane, Norwich, NR4 7UY	Kneale Metcalf
Bristol Royal Infirmary, Marlborough Street, Bristol, BS2 8HW	Julie Dovey
Lancaster Royal Infirmary, Ashton Road, Lancaster, LA1 4RP	Pradeep Kumar
Southampton General Hospital, Tremona Road, Southampton, SO16 6YD	Giles Durward
Scunthorpe General Hospital, Cliff Gardens, Scunthorpe, DN15 7BH	Amit Bannerjee
Whiston Hospital, Dept Care of the Elderly, Prescot, Liverpool, L35 5DR	Vinod Kumar
Newton Abbott Hospital, Jetty Marsh, Newton Abbott, TQ12 2TS	Debs Kelly
Sheffield Teaching Hospitals, Royal Hallamshire Hospital, Sheffield, S10 2JF	Catrin Blank

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

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*

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



**Mr Dean Beattie**  
**Acting Co-ordinator**

Email: dean.beattie@nhs.net

Copy to: *Professor Philip M. W. Bath, University of Nottingham  
Clinical Trials Unit, MHRA*