



## National Research Ethics Service

### South East Research Ethics Committee

South East Coast Strategic Health Authority  
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29 March 2010

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:** SA01/10 8 March 2010

**Amendment date:** 08 March 2010

Thank you for submitting the above amendment, which was received on 11 March 2010.

Research Site	Principal Investigator / Local Collaborator
Kingston Hospital NHS Trust, Galsworthy Road, Kingston Upon Thames, Surrey KT2 7QB	Lillian Choy
York Hospital, Acute Stroke Unit, Wiggington Road, York, YO31 8HE	John Coyle
Royal United Hospital, Combe Park, Bath, BA1 3NG	Louise Shaw
Raigmore Hospital, Old Perth Road, Inverness, IV2 3UJ	Paul Findlay
Macclesfield District General Hospital, Victoria Road, Macclesfield, Cheshire, SK10 3BL	Moe Sein
Epsom & St Helier University Hospitals NHS Trust, Epsom & St Helier, Wrythe Lane, Carshalton, SM5 7AA	Valerie Jones
Birmingham Heartlands Hospital, Bordesley Green East, Birmingham, B9 5SS	David Sandler

Gloucestershire Royal Hospital, Stroke Service, Great Western Road, Gloucester, NE7 7DN	Dipanker Dutta
University Hospitals Birmingham NHS Foundation, Selly Oak Hospital, Acute Stroke Unit Ward A1, Raddlebarn Road, Selly Oak, B29 6JD	Don Sims
The Pennine Acute Hospital NHS Trust, Fairfield General Hospital, Fairfield House (Rm 3.50), Rochdale Old Rd, Bury B29 7TD	Robert Namushi
Mount Gould Hospital (Rehab), Mount Gould Rd, Plymouth, PL4 7QD	Azlisham Modh Nor
East Kent Hospitals University NHS Trust, Queen Elizabeth the Queen Mother Hospital, St Peters Road, Margate, CT9 4NA	Gunaratnam Gunathathilagan
Stockport NHS Foundation Trust, Stepping Hill Hospital, Poplar Grove, Stockport SK2 7JE	Kamiran Dizayee
King's College Hospital NHS Foundation Trust, Denmark Hill, London, SE5 9NR	Dulka Manawadu
Torbay Hospital, c/o Simpson Ward, Lawes Bridge, TQ2 7AA	Isam Sayed Mahmoud Salih
Ipswich Hospitals, Heath Road, Ipswich, Suffolk, IP4 5PD	Jospeh Ngeh
William Harvey Hospital, Willesborough, Ashford, TN24 0LZ	David Hargroves
Scarborough General Hospital, Woodlands Drive, Scarborough, Yorkshire, YO12 5QL	John Paterson

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



**Mr Dean Beattie**  
**Committee Co-ordinator**

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Copy to: *Chief Investigator*  
*Mr Paul Cartledge*  
*Clinical Trials Unit, MHRA*