14 DEC 2010

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NHS

National Research Ethics Service

South East Research Ethics Committee
South East Coast Strategic Health Authority
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08 December 2010

Ms Margaret Adrian
TARDIS Trial – Nurse Co-ordinator
University of Nottingham
Division of Stroke Medicine
CSB, City Hospital Campus,
Hucknall Rd,
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:	**31350**
EudraCT number:	**2007-006749-42**
Amendment number:	**SA06/10 12 November 2010**
Amendment date:	**17 November 2010**

Thank you for submitting the above amendment, which was received on 22 November 2010.

Research Site	Principal Investigator / Local Collaborator
Kings Mill Hospital, Mansfield Road, Sutton	Martin Cooper

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

Sophie Vella
Assistant Co-ordinator

Email: sophievella@nhs.net

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