



Health Research Authority
National Research Ethics Service

NRES Committee London - South East

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21 April 2015

Hayley Foster
Trial Manager
Stroke, Division of Clinical Neuroscience
University of Nottingham
City Hospital Campus
Hucknall Road
Nottingham
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Dear Hayley Foster

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: 08/H1102/112

Protocol number: 31350

EudraCT number: 2007-006749-42

Amendment number:

Amendment date:

IRAS project ID:

The Substantial Amendment changes PI at:

- Northampton General Hospital Trust; Declan O'Kane (replacing Dr Melanie Blake)
- Gateshead Health NHS Foundation Trust; Bernard Esi (replacing Dr T Cassidy)
- Barnsley NHS Foundation Trust; Ashraf Ahmed (replacing Dr Mohammed Albazzaz)
- Bedford Hospital NHS Trust; Hlaing Ni (replacing Mohammed Wasil)

Thank you for submitting the above amendment, which was received on 17 April 2015.

<i>Research site</i>	<i>Principal Investigator / Local Collaborator</i>
Northampton General Hospital Trust	Declan O'Kane
Gateshead Health NHS Foundation Trust	Bernard Esi
Barnsley NHS Foundation Trust	Ashraf Ahmed
Bedford Hospital NHS Trust	Hlaing Ni

The amendment relates solely to the addition of new investigators 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 investigators, 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.

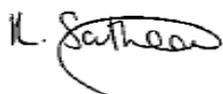
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees 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



Katie Southeard
REC Assistant

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Copy to: *Professor Philip M. W. Bath, University of Nottingham*