



Health Research Authority
National Research Ethics Service

NRES Committee London - South East

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16 June 2015

Professor Philip M. W. Bath
Professor of Stroke Medicine
University of Nottingham
Division of Stroke Medicine - Research Dept
Clinical Sciences Building
City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

Dear Professor Bath

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: SA02/15

Amendment date: 16 June 2015

IRAS project ID:

The Substantial Amendment removes 9 sites:

1. Dorset County Hospitals
2. North Devon District Hospital
3. Basildon University Hospital
4. Weston Area Health NHS Trust
5. Watford General Hospital
6. James Paget University Hospital
7. Blackpool Victoria Hospital
8. Harrogate District General Hospital
9. Warrington Hospital

Changes of PI at 2 sites:

1. Lincoln County Hospital (previously Dr Simon Leach)
2. Royal Bournemouth Hospital (previously Damian Jenkinson)

Thank you for submitting the above amendment, which was received on 16 June 2015.

<i>Research site</i>	<i>Principal Investigator / Local Collaborator</i>
Dorset County Hospitals	Rob Williams
North Devon District Hospital	Mervyn Dent

Basildon University Hospital	Ravi Rangasamay
Weston Area Health NHS Trust	Harbans Bhakri
Watford General Hospital	Thurul Attygalle
James Paget University Hospital	Mazhar Zaidi
Blackpool Victoria Hospital	James McIlmoyle
Harrogate District General Hospital	Sean Brotheridge
Warrington Hospital	Karim Mahawish
<i>Change of PI</i>	<i>Principal Investigator / Local Collaborator</i>
Lincoln County Hospital	Mohammed Soliman
Royal Bournemouth Hospital	Becky Jupp

The amendment relates solely to the removal sites and change of 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 removal sites and change of 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
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Yours sincerely



Katie Southeard
REC Assistant

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