

NRES Committee London - South East

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03 September 2012

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: SA06/11, Protocol V1.3, 20/12/2011

Amendment date: 22 December 2011

The above amendment was reviewed at the meeting of the Sub-Committee held on 03 May 2012 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
TARDIS GP Letter	1.2 (tracked changes)	20 December 2011
TARDIS GP Letter	1.2	20 December 2011
Annex 1 - Clinical Trial Application Form		
Participant Consent Form: TARDIS: Proxy Relative Consent Form	1.5 (tracked changes)	20 December 2011
Participant Consent Form: TARDIS: Proxy Relative Consent Form	1.5	20 December 2011

Participant Consent Form: TARDIS: Agreement Form after Proxy Relative or Legal Representative Consent	1.5 (tracked changes)	20 December 2011
Participant Consent Form: TARDIS Agreement Form After Proxy Relative or Legal Representative Consent	1.5	20 December 2011
Participant Information Sheet: TARDIS Relative Information Sheet	1.5	20 December 2011
Participant Information Sheet: TARDIS Participant Information Sheet after RIS	1.5 (tracked changes)	20 December 2011
Participant Information Sheet: TARDIS Participant Information Sheet	1.5	20 December 2011
Participant Information Sheet: TARDIS Participant Information Sheet	1.5 (tracked changes)	20 December 2011
European Commission Notification of Substantial Amendment Form	SA06/11, Protocol V1.3, 20/12/2011	22 December 2011
Covering Letter		
Substantial Protocol Amendment Summary of Changes Version 1.3		
Participant Consent Form: TARDIS Patient Consent Form	1.5 (Tracked Changes)	20 December 2011
Participant Consent Form: TARDIS Patient Consent Form	1.5	20 December 2011
Participant Consent Form: TARDIS Independent Physician Consent Form	1.5 (tracked changes)	20 December 2011
Participant Consent Form: TARDIS Independent Physician Consent Form	1.5	20 December 2011
Participant Information Sheet: TARDIS - Independent Physician Information Sheet	1.5 (tracked changes)	10 February 2011
Protocol	1.3	20 December 2011
Protocol	1.3 (tracked changes)	20 December 2011
Participant Information Sheet: TARDIS Independent Physician Information Sheet	1.5	20 December 2011

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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

PP 

Professor David Caplin
Chair

E-mail: janhoi.mcgregor@imperial.nhs.uk

Enclosures: List of names and professions of members who took part in the review

*Copy to: N/A. R&D contact not specified in database.
Mr Paul Cartledge*

NRES Committee London - South East

Attendance at Sub-Committee of the REC meeting on 03 May 2012

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Professor David Caplin	Physicist	Lay
Mr Roy Sinclair	Pharmacist	Expert