NHS

North West Research Ethics Committee

NHS North West
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1 March 2007

Dr J Armitage
Clinical Trial Service Unit
Richard Doll Building
University of Oxford
Old Road Campus
Headington
OXFORD OX3 7LF

Dear Dr Armitage

Full title of study:	**ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and of omega-3 fatty acid supplementation versus placebo, for primary prevention of cardiovascular events in people with diabetes**
REC reference number:	**MREC 03/8/087**
Protocol number:	***N/A***
EudraCT number:	**2004-000991-15**
Amendment number:	**CTSUASCEND2, version 8.0**
Amendment date:	**01 February 2007**

The above amendment was reviewed at the meeting of the Sub-Committee held on 13 February 2007.

Ethical opinion

The amendment sought approval for hospital collaborators, GPs or practice nurses to offer a standard "invitation pack" to potentially eligible participants when they attended their clinic visit for routine care. In addition it was proposed that patients who are already participating in the study be given an option to recommend friends or relatives who may be interested in participating and that potential participants be allowed to volunteer themselves should they hear about the study via another route.

The study recruitment documents to be included in the "invitation pack" had been revised, plus two new versions of the letter of invitation letter had been produced to reflect the above amendments and had also been submitted for review.

Minor textual changes to the Protocol had also been made.

A comprehensive rationale had been provided by the applicant In support of the amendment.

The Sub-Committee had no ethical difficulties with the proposed amendment.

The members of the Committee present 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
Covering Letter		01 February 2007
Annex 2 Notification of Amendment (CTIMPs)	CTSUASCEND2, version 8.0	01 February 2007
J2: Summary of Proposed Amendment	8	01 February 2007
J3: List of modified documents	8	01 February 2007
Enclosure 1: Standard CTSU Invitation Letter	V1	01 February 2007
Enclosure 2a: A15-3 GP Letter & Reply Form - run-in eligible patient	V2	01 February 2007
Enclosure 2b: A15-4 GP Letter - run-in NOT eligible	V2	01 February 2007
Enclosure 3: Friend or Relative Invitation Letter	V1	01 February 2007
Enclosure 4: Participant Information Sheet	V8	01 February 2007
Enclosure 5: Protocol	V8	01 February 2007
Enclosure 6: Protocol Summary	V8	01 February 2007

Membership of the Committee

The members of the Committee who were present at the meeting 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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

03/8/087:	**Please quote this number on all correspondence**

Yours sincerely

Noel Graham
Deputy Committee Co-ordinator

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Enclosures:- List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to:- Clinical Trials Unit - MHRA