North West Multi-centre Research Ethics Committee

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28 June 2004

Dr J Armitage
ASCEND
Clinical Trial Service Unit
The University of Oxford
Harkness Building
Radcliffe Infirmary
OXFORD OX2 6HE

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**
Amendment number:	**CTSUASCEND1-1 – version 7**
Amendment date:	**19 May 2004**

The above amendment was reviewed by a Sub-Committee of the North West Multi-centre Research Ethics Committee at the meeting held on 22 June 2004.

Ethical opinion

The amendment requested approval for the introduction of an optional urine sample to be collected during the pre-randomisation run-in period, and at least once during the follow-up period in a random sample of participants.

Approval was also sought for a number of minor textual changes to the study protocol to accommodate the additional urine samples and other points of clarification.

The Sub-Committee saw no ethical difficulties with the proposed changes.

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

Approved documents

The documents reviewed and approved at the meeting were: -

- **Covering letter from Dr Jane Armitage - dated 01/06/04**
- **Notification of Amendment Form – signed and dated 01/06/04**
- **Summary of Proposed Amendment**
- **Document Changes for Re-Submission to the North West MREC**

Attachment 1
- **Revised B15-2: Participant invitation letter, Screening Questionnaire and Consent Form (identified from general practice) – V3 - 140504**
- **Approved B15-2: Participant invitation letter, Screening Questionnaire and Consent Form (identified from general practice) – V1 - 170903**

Attachment 2
- **Revised B17-1: ASCEND Patient Information Leaflet – V7 – 070504**
- **Approved B17-1: ASCEND: Invitation to join a large medical research project – V6 – 201103**

Attachment 3
- **Revised B17-2: ASCEND: Blood & Urine Sampling Information Leaflet – V5 – 210504**
- **Approved B17-2: Supplementary Information Leaflet – ASCEND: Information about blood sampling – v4 - 201103**

Attachment 4
- **Revised B17-3: ASCEND: Study Treatment Information Leaflet – V2 - 210504**
- **Approved B17-3: Study treatment information – Version 1 – 170903**

Attachment 5
- **Revised B18-2: ASCEND: Blood & Urine Sample Consent Form – V3 – 210504**
- **Approved B18-2: Consent for blood collection, storage and analysis – Version 2 – 06/08/03**

Attachment 6
- **Revised B22-1: Participant letter and Randomisation Questionnaire – V2 - 200504**
- **Approved B22-1: Participant letter and Randomisation Questionnaire – V1 - 170903**

Attachment 7
- **Revised B22-2: Participant Follow-up letter and Questionnaire – V2 - 190504**
- **Approved B22-2: Participant Follow-up letter and Questionnaire – V1 - 170903**

Attachment 8
- **Amendments to ASCENT Protocol – V6 - 201103**
- **Revised Protocol – version 7 – dated 19/05/04**

Site-specific issues

It was noted as part of the review that the amendment has no implications for the suitability of local investigators, sites or facilities. You are not required to obtain any further site-specific assessment, and there is no need to inform Local Research Ethics Committees of the amendment.

Approval of host organisations

Local principal investigators or research collaborators should notify their host organisations of this amendment and check whether it affects local management approval of the research.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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 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.

REC reference number: MREC 03/8/087 Please quote this number on all correspondence

Yours sincerely

C.A. Stokes

Cathie Stokes
Committee Administrator

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

List of names and professions of members who were present at the meeting

Dr Paul R Kelsey – Chairman – Consultant Haematologist

Professor Alistair Burns – Professor of Old Age Psychiatry
Mr Alan Rigby – Medical Statistician