



National Research Ethics Service

North West Research Ethics Committee

NHS North West
Room 155 - Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: (0161) 237 2394 / 2152

Fax: (0161) 237 2383

23 May 2007

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

Dear Dr Armitage

| | |
|--------------------------|--|
| Study title: | 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: | 03/8/087 |
| Protocol number: | CTSUASCEND, version 8.0_010207, 2007-02-01 |
| EudraCT number: | 2004-000991-15 |
| Amendment number: | CTSUASCEND3, version 8.0_010207, 2007-05-08 |
| Amendment date: | 08 May 2007 |

The above amendment was reviewed at the meeting of the Committee held on 15 May 2007.

Ethical opinion

The amendment sought approval to allow the use of posters/flyers for potential participants to be made available in clinic waiting areas. They would give a brief description of the ASCEND study and invite potentially eligible volunteers to contact the co-ordination centre.

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 | | 08 May 2007 |
| Annex 2 Notification of Amendment (CTIMPs) | CTSASCEND3, version 8.0_010207, 2007-05-08 | 08 May 2007 |
| Summary of Proposed Amendment | CTSASCEND3, version 8.0_010207, 2007-05-08 | 08 May 2007 |
| Poster | V1_080507 | 08 May 2007 |
| Participant Flyer | V1_080507 | 08 May 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.

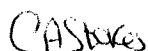
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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.

MREC 03/8/087:

Please quote this number on all correspondence

Yours sincerely



Cathie Stokes
Committee Co-ordinator

E-mail: - northwest.mrec@northwest.nhs.uk

Enclosure: - 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

North West Research Ethics Committee

Members Sub-Committee Attendance Sheet – 15 May 2007

| Member | Profession | In attendance | Written comments submitted |
|-----------------------------|---|---------------|----------------------------|
| Professor Hazel Biggs | Professor of Medical Law | | |
| Mrs Arlene Blanchard | Lay Member | | |
| Mr James Bruce | Consultant Surgeon | | |
| Ms Chris Burgess | Lay Member | ✓ | |
| Mr Barry Clift | Senior Occupational Therapist | ✓ | |
| Dr Sally Furnish | Chartered Clinical Psychologist | | |
| Dr Ravi Gulati | Consultant Physician | ✓ | |
| Dr Donal Manning | Chairman Consultant Paediatrician | | |
| Dr Cameron Munro | General Practitioner | ✓ | |
| Mrs Margaret Norval | Chief Pharmacist | ✓ | |
| Dr Jane Pearson | Vice-Chair Research & Development Manager | ✓ | |
| Professor Elizabeth Perkins | Lay Member | ✓ | |
| Mr Alan Rigby | Medical Statistician | | |
| Dr Tim Sprosen | Medical Researcher / Epidemiologist | ✓ | |
| Mr Ric Swindell | Medical Statistician | ✓ | |
| Mr Robert Woodward | Consultant Oral & Maxillofacial Surgeon | | |