NHS

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

21 July 2008

Dr J Armitage
Clinical Trial Service Unit (CTSU)
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:	**CTSUASCEND4, version 8.0_010207, 2008-06-10**
Amendment date:	**17 June 2008**

The above amendment was reviewed at the meeting of the Committee held on 08 July 2008.

Ethical opinion

The amendment (CTSUASCEND4, version 8.0_010207, 2008-06-10) sought approval for an updated Study Treatment Information Leaflet (V3.0_160508) to provide clarification on some of the information contained therein (i.e. the storage of study medication; the management of minor symptoms; and the use of blister packs containing study medication), and to provide an updated list of aspirin-containing proprietary medications that should be avoided whilst participating in the trial.

It was intended that the revised leaflet would be sent to all currently randomised participants, in addition to patients newly entering the trial.

The 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 - from Dr Jane Armitage		12 June 2008
Annex 2 Notification of Amendment (CTIMPs): CTSUASCEND4, version 8.0_010207, 2008-06-10		17 June 2008
Summary of Proposed Amendment	Version 8	12 June 2008
List of modified documents	Version 8	12 June 2008
Study Treatment Information Leaflet - revised - with changes highlighted	V3.0	16 May 2008
Study Treatment Information Leaflet - revised - with changes incorporated	V3.0	16 May 2008
Study Treatment Information Leaflet - approved	V2	21 May 2004

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

E-mail: noel.graham@northwest.nhs.uk

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

North West Research Ethics Committee

Members Attendance Sheet – 8 July 2008

Member	Profession	In attendance	Written comments submitted
Mrs Arlene Blanchard	Lay Member		
Mr James Bruce	Consultant Surgeon		
Ms Chris Burgess	Lay Member	✔	
Professor Caroline Carlisle	Professor of Education in Nursing and Midwifery	✔	
Dr Brian Faragher	Medical Statistician	✔	
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 Fiona O'Neill	Medical Sociologist / Bioethicist	✔	
Professor Elizabeth Perkins	Lay Member	✔	
Mr Alan Rigby	Medical Statistician		
Dr Tim Sprosen	**Vice-Chairman** Medical Researcher / Epidemiologist	✔	
Mr Robert Woodwards	Consultant Oral & Maxillofacial Surgeon		