

CLINICAL TRIAL OF AN INVESTIGATIONAL MEDICINAL PRODUCT (CTIMP)

ANNUAL PROGRESS REPORT TO MAIN RESEARCH ETHICS COMMITTEE

To be completed in typescript and submitted by the Chief Investigator. Please send this report only to the main REC. For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

Name:	Professor Jane Armitage
Address:	Clinical Trial Service Unit Richard Doll Building University of Oxford Old Road Campus Oxford OX3 7LF
Telephone:	01865 743810
E-mail:	jane.armitage@ctsuo.ox.ac.uk
Fax:	01865 743981

2. Details of study

Full title of study:	ASCEND: (A Study of Cardiovascular Events in Diabetes) 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.
Name of main REC:	North West Multi-centre Research Ethics Committee
REC reference number:	MREC 03/8/087
Date of favourable ethical opinion:	29 December 2003
Sponsor:	University of Oxford
EudraCT Number:	2004-000991-15

3. Commencement and termination dates

Has the study started in the UK?	Yes
If yes, what was the actual start date in the UK?	15 March 2005
If no, what are the reasons for the study not commencing in the UK? What is the expected start date?	

Has the study finished? <i>If yes, complete and submit EudraCT "Declaration of end of trial" form at Annex 3 to ENTR/CT1, available at: https://eudract.emea.europa.eu/document.html</i>	No
If no, what is the expected completion date? <i>If you expect the study to overrun the planned completion date this should be notified to the main REC for information.</i>	2017
If you do not expect the study to be completed, give reason(s)	

4. Site information

Number of UK research sites proposed in original application:	100 NHS Trusts, 200 Primary Care Trusts
Number of UK research sites recruited to date:	70 NHS Trusts, 181 Primary Care Trusts
Do you plan to increase the total number of UK sites proposed for the study? <i>The addition of any new sites not listed in the original applications to the REC and the MHRA should be notified to both bodies by submitting a substantial amendment using the form at Annex 2 to ENTR/CT1, available at https://eudract.emea.europa.eu/document.html</i>	No

5. Recruitment of participants

* Number of participants recruited:	<i>Proposed in original application: 10,000 Actual number recruited to date: 15,480</i>
* Number of participants completing trial:	<i>Actual number completed to date:0</i>
* Number of withdrawals from trial to date due to:	
(a) withdrawal of consent	0
(b) loss to follow-up	0
(c) death (where not the primary outcome)	140
Total study withdrawals:	140
*Number of treatment failures to date (prior to reaching primary outcome) due to:	
(a) adverse events	0
(b) lack of efficacy	0
Total treatment failures:	0

** In the case of international trials, please provide separate figures for UK and non-UK participants.*

Have there been any serious difficulties in recruiting participants?	No: initially slower than anticipated but now completed recruitment.
If yes, give details:	
Do you plan to increase the planned recruitment of participants into the study? <i>Any increase in planned recruitment should be notified to the main REC as a substantial amendment for ethical review.</i>	No

6. Safety reports

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in the UK?	No
Have these SUSARs been notified to the Committee within 7/15 days under Article 17 of EU Directive? <i>If no, please arrange urgently and give reasons for late notification.</i>	N/A
What is the reporting date for periodic safety reports to the main REC during this trial? <i>This is the date of first authorisation of the trial in any EU member state or, if the sponsor is the Marketing Authorisation Holder, the International Birth Date for the product.</i>	DDX issued on 18 November 2003; automatically transferred to CTA on 1 May 2004
Has a 6 monthly safety report been submitted? <i>Applies only to commercial sponsors undertaking this trial or other trials of the IMP outside the UK.</i>	Not applicable
Has the Annual Safety Report been submitted?	Yes: DSUR submitted concurrently with this progress report
When is the next ASR due?	February 2013

7. Amendments

Have any substantial amendments been made to the trial during the year?	Yes
If yes, please give the date and amendment number for each substantial amendment made.	Amendment 7_2011-12-01

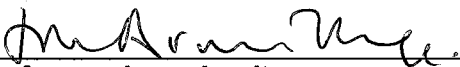
8. Serious breaches of the protocol or Good Clinical Practice

Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year? <i>Under the Clinical Trials Regulations, all serious breaches must be notified to the MHRA GCP inspectors within 7 days of the matter coming to the sponsor's attention.</i>	No
If yes, please give the date of each notification to the MHRA. <i>Please provide the REC with a copy of each notification for information (unless previously notified).</i>	

9. Other issues

Are there any other developments in the trial that you wish to report to the Committee?	No
Are there any ethical issues on which further advice is required? <i>If yes to either, please attach separate statement with details.</i>	No

10. Declaration

Signature of Chief Investigator:	
Print name:	Professor Jane Armitage
Date of submission:	29-02-2012