

5. Medical History

5.1 Has a doctor ever told you that you had any of the following?

a) Diabetes mellitus (i.e. "sugar" diabetes)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Please cross ONE box only for each question
b) Heart attack	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
c) Angina (chest pain from the heart)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
d) Stroke or ministroke (sometimes called TIA)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
e) Coronary artery bypass operation (CABG or "cabbage")	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
f) Coronary angioplasty ("balloon", "stent" insertion or PTCA)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
g) Other arterial surgery or angioplasty (e.g. leg bypass) (Do not include angiogram)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

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If **Yes**, please specify:

h) Liver disease (active or chronic, or cirrhosis)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If **Yes**, please specify:

i) Cancer (e.g. skin, breast, lung, bowel etc)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If **Yes**, please give the type of cancer:

j) Other serious illness (e.g. kidney disease)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If **Yes**, please specify:

5.2 In the last 6 months have you been in hospital with, or has a doctor said you have:

a) Active peptic (stomach or duodenal) ulcer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
b) Bleeding from the stomach or bowel?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

6. Current Medication

As a participant in ASCEND, you would be asked not to use NON-STUDY aspirin, medications containing aspirin or blood thinning drugs on a regular basis (i.e. more than one day per week) unless this becomes necessary.

6.1 Do you currently take any of the following regularly?

a) Aspirin (e.g. Anadin, Caprin, Disprin, Imazin, PostMI)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Please cross ONE box only for each question
b) Warfarin (Marevan), Acenocoumarol (Nicoumalone, Sinthrome) or Phenindione	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

6.2 Are you known to be allergic to aspirin or omega-3 fatty acid (fish oil) supplements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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6.3 As a participant in ASCEND would you be willing to avoid using medications containing aspirin? (N.B. you could use paracetamol instead for pain relief)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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Need help completing this form? Please call Freefone 0800 585323

Please read this **Agreement to Participate**, and if you are willing then please CROSS the boxes, SIGN and DATE the form using blue or black ink, and return it in the FREEPOST envelope provided.

7. Agreement to Participate

Please cross (X) **EVERY box** to confirm that you have read and understood the following:

<input type="checkbox"/>	I have read and understood the leaflet “ ASCEND: Invitation to join a large medical research project ”
<input type="checkbox"/>	I have had an opportunity to telephone the Freefone number 0800 585323 and ask any relevant questions, and all my questions have been answered to my satisfaction (or I decided that I did not need to ask any questions)
<input type="checkbox"/>	I understand that my participation in the ASCEND study is voluntary and that I am free to withdraw from the study at any time without my medical care or rights being affected
<input type="checkbox"/>	I understand that information about my progress in the ASCEND study will be recorded on a computer database, and that these data will be stored securely and confidentially on a computer at Oxford University
<input type="checkbox"/>	I agree that information about any serious illnesses (such as heart attacks, strokes or cancers) may be supplied in confidence to the study coordinators by my own doctors and by central registries for use in the ASCEND study
<input type="checkbox"/>	I agree that my hospital and other health records may be looked at in confidence by authorised individuals from the ASCEND study and by regulatory authorities to check the study is being carried out correctly
<input type="checkbox"/>	I understand that my GP will be informed about this provisional agreement to participate in the ASCEND study, and that in about 2 months time I will have another opportunity to decide whether or not I want to join the long-term part of the study

I am happy to take part in ASCEND:

Signature:

(Please use blue or black ink)

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& **PRINTED** name:

Today's date:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Day			Month			Year			

Please check that you have answered every question, and signed and dated the form. Return the completed form in the Freepost envelope provided (no stamps needed) to:

ASCEND, FREEPOST NAT13900, Harkness Building, Radcliffe Infirmary, OXFORD, OX2 6BR

If you have any questions about the study, please contact the coordinating centre in Oxford on FREEFONE: 0800 585323 (preferably during office hours 9 am – 5 pm, Monday to Friday)

If this questionnaire indicates that you are suitable to enter the preliminary part of ASCEND, a box containing ASCEND tablets (aspirin or placebo) and capsules (one or other natural oil) will be mailed to you. A copy of this Agreement to Participate, for you to keep, will also be mailed.

If the questionnaire suggests that the study medications may not be suitable for you, then we shall write and tell you.

Thank you very much

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**Attachment 1: Amendments to B15-2
Participant invitation letter, Screening Questionnaire
and Consent Form (identified from general practice)**

Clinical Trial Service Unit
Harkness Building
Radcliffe Infirmary
Oxford
OX2 6HE

ASCEND Office Tel: 01865 404888
ASCEND Office Fax: 01865 404871
Freefone: 0800 585323
Email: ascend@ctsu.ox.ac.uk
Web site: www.ctsu.ox.ac.uk/ascend

Ref: 234-5678

Dear _____

ASCEND: A Study of Cardiovascular Events in Diabetes

We are writing to invite you to participate in the ASCEND research study of the prevention of heart attacks and strokes in people with diabetes. In this practice we are working with the *Royal Yorclay Infirmary NHS Trust* and Oxford University's Clinical Trial Service Unit to help identify suitable people for this nationwide study. So, we are writing to all those people on our local diabetes register aged over 40 who may be suitable, in order to find out whether they might be interested in taking part. The purpose of the study is to assess whether aspirin and/or naturally-occurring oils are useful for preventing heart attacks and strokes in people with diabetes who have not had circulatory problems.

Please read the enclosed Information Leaflet entitled "ASCEND: Invitation to join a large medical research project", it is then up to you whether or not you would like to take part. If you might like to, then please complete the attached questionnaire. Based on your answers, the study coordinators will write and tell you whether or not you would be suitable.

If you have any questions regarding the study you may telephone the study co-ordinators (Dr Jane Armitage or Dr Louise Bowman) on Freefone 0800 585323. Alternatively you may wish to discuss matters with me or our practice nurse before deciding whether to join. If you would like to join the study then please complete the questionnaire and sign the Agreement to Participate. We hope you will decide to take part in ASCEND. If you do not want to participate then please indicate this on the questionnaire on the back of this letter, so that you do not get approached again. Then please return the questionnaire in the Freepost envelope provided. (Refusal to take part will have no effect on your usual medical care.)

Thank you for your help.

Yours sincerely

Dr Ronald Atkinson
General Practitioner
East Yorclay Health Centre

Dr David Pleat
Consultant Diabetologist
Royal Yorclay Infirmary NHS Trust

Enc: Information Leaflet
Freepost envelope