

ASCEND: A Study of Cardiovascular Events in Diabetes

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ASCEND: The Research Question

ASCEND: A Study of Cardiovascular Events in Diabetes

- For people with diabetes who have not yet had a heart attack or stroke:
 - Is low-dose aspirin beneficial?
 - Are omega-3 fish oils beneficial?
 - Are these treatments safe?



The Study Design:

2x2 factorial design randomised trial of aspirin vs placebo and omega-3 FA vs placebo

	Aspirin tablets	Placebo tablets	
Omega-3 Fatty acids (FA) capsules	3750 Aspirin + Omega-3 FA	3750 Omega-3 FA	7500 Omega-3 FA
Placebo capsules	3750 Aspirin	3750 Neither	7500 Placebo
	7500 Aspirin	7500 Placebo	

The Problem



The Solution

- Streamlined
- Cost effective
- Simple eligibility criteria
- Mail-based trial design

No study clinics required







The Funding

- British Heart Foundation special project grant £2.7 million
- Bayer/Abbott: study drug and funding for packaging

Trial coordination

- Sponsor: University of Oxford
- Steering Committee
- Independent Data Monitoring Committee

The Next Problem

- Identification of potentially eligible study participants
 - Central databases
 - Hospital-based registers
 - Regional registers (eg retinopathy screening)
 - Other approaches
 - Invited direct from GP
 - Self-nominate/friends & family

Central recruitment: invitations sent to potentially eligible patients

- Patients mailed
 - Invitation letter (from lead clinician)
 - Information leaflet
 - Screening questionnaire
 - Consent form
- 24 hour telephone service to deal with any questions about the study

Need help complete

Please read this Agreement
SIGN and DATE the form using

Please cross (X) EVERY box

The Pennine Acute Hospitals



NHS Trust

Old Road Campus
Healdington, Oxford
OX3 7LF

Office Tel: 01865 743988
Office Fax: 01865 743981

Freephone: 0800 585323

E-mail: ascend@penn.ac.uk

Website: www.penn.ac.uk/ascend

Mr Thomas White
24 Raspberry Road
Garsington
Oxfordshire
OX4 3TR

Dear Mr White,

26 January 2010 +

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. At the Diabetes Centre at The Royal Oldham Hospital, we are working with Oxford University's Clinical Trial Service Unit to help identify suitable people for this nationwide study. So, we are writing (having first informed your GP, Dr Ross Gardener) to all those people on our local diabetes register who are aged over 40 and 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 would 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 (Professor Jane Armitage or Dr Louise Bowman) on Freephone 0800 585323. Alternatively, you may wish to discuss matters with your GP or diabetes nurse before deciding whether to join. If you do not want to take part this will have no effect on your usual medical care. If you want 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. In either case, please return the questionnaire in the Freepost envelope provided.

- I have read and understood the leaflet "ASCEND: Invitation to join a large medical research project"
- I have had an opportunity to telephone the Freephone number 0800 585323 and ask any relevant questions. All my questions have been answered to my satisfaction OR I decided that I did not need to ask any questions
- 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
- 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
- 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 NHS and other central registries for use in the ASCEND study
- 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
- 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:

0800 585323 Freephone number to call

Signature:

[Signature box]

(Please use blue or black ink)

A PRINTED name:

[Name box]

Today's date:

[Date box: 20/01/10]

Please check that you have answered every question, and signed and dated the form.

Return the completed form in the

Freepost RLUJ-TKES-SURB, ASCEND
Old Road Campus, Healdington, Oxford

If you have any questions about the study
FREEPHONE: 0800 585323 (preferably)

If this questionnaire indicates that you
a box containing ASCEND tablets (as
will be mailed to you. A copy of this
mailed.

If the questionnaire suggests that the
shall write and tell you.

Dr Deepak Bhatnagar

Dr Deepak Bhatnagar
Consultant/Senior Lecturer in Diabetes & Metabolism
Royal Oldham Hospital

Dr Biswa Mishra

Dr Biswa Mishra
Consultant Diabetologist and Endocrinologist
Royal Oldham Hospital

Thank you very much

Freepost envelope
ONS (V1, 15, 061120) P 0 82147111
0800 585323 Freephone number to call



ASCEND: Screening Questionnaire

INSTRUCTIONS FOR COMPLETION

Please complete the questionnaire in BLOCK CAPITALS using blue or black ink.

Please place a cross in the appropriate box, e.g. Yes No

(If you make a mistake, fill the entire box and mark the correct box, e.g. Yes No)

OR write clearly in the appropriate boxes, e.g.

1. Contact Details

Please write your name and contact details clearly in the boxes provided.

Title: Mr Mrs Ms Miss Other

First name(s):

Surname:

Address:

Postcode:

Home telephone number (inc. code):

Daytime telephone number (inc. code):

2. Personal Details

Date of birth: / / Sex: Male Female +

3. Joining ASCEND

Please read the enclosed leaflet (ASCEND: Invitation to join a large medical research project), and indicate whether you are interested in taking part in ASCEND: Yes No

If you answered YES, then please complete ALL the remaining sections of this questionnaire, sign and date the form, and return it in the FREEPOST envelope provided.

If you answered NO, then return the questionnaire in the FREEPOST envelope provided (but do not complete the remaining sections).

4. GP Details

Please give your GP's surname and initials, as well as the address of the GP practice.

GP surname: GP initials:

Address:

Postcode:

+

Need help completing this form? Please call Freephone 0800 585323

+

5. Medical History

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

- | | | | |
|---|------------------------------|-----------------------------|---|
| a) Diabetes, Type 1 or Type 2 (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"/> | |

If Yes, please specify:

- h) Liver disease (active or chronic, or cirrhosis) Yes No

If Yes, please specify:

- i) Cancer within the last 5 years (e.g. skin, breast, lung, bowel etc.) Yes No

If Yes, please give the type of cancer:

- j) Other serious illness Yes No

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 No

- b) Bleeding from the stomach or bowel? Yes No

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 (Nicooumalone, 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 No

6.3 Are you willing to avoid medications containing aspirin (apart from ASCEND study treatment) during the course of the study? Yes No

(N.B. you could use paracetamol instead for pain relief)

+

Pre-randomisation run-in phase

- GP informed that patient has entered run-in; option to withdraw
- Blood kit mailed during run-in period
- Randomisation form mailed after 6 weeks

Baseline blood samples (optional)



- 22,900 blood and urine kits sent out
- 13,000 participants returned samples
- 11,500 from randomised participants (74%)
- HbA1C, TC, HDL c, Apo A1, Apo B, urinary albumin/creatinine measured on fresh samples
- Urine, plasma, red cells and genetic material stored long-term



Need help completing this form? Please call Freephone 0800 585323

7. Current Medication

7.1 Please list your current medication as prescribed by your doctor (names only, doses not required). Please do not list any medication (e.g. aspirin) you have stopped to enter ASCEND.

7.2 Please list any other treatments you take regularly (i.e. more than twice a week), for example, pain killers, vitamins, supplements, over-the-counter tablets or capsules.

8. Alternative Contact

It would be very helpful for us if you could provide the details of a relative, friend or neighbour living at a different address who we could contact if for any reason we were unable to get hold of you. Please indicate their relationship to you and write their contact details clearly in the boxes provided.

Relationship: Relative Friend Neighbour Other

Title: Mr Mrs Ms Miss Other

First name(s)

Surname

Address

Address

Postcode

Telephone number (inc. code)

9. Continuing in ASCEND

Thank you for completing the questionnaire. If you are happy to continue taking the ASCEND tablets and capsules for the next 5 years, then please SIGN and DATE the form below using blue or black ink, and return it in the FREEPOST envelope provided. Within about 2 weeks of us receiving your questionnaire, if eligible, you will receive a new box of ASCEND medication and will be asked to take one tablet and one capsule daily.

I am happy to take part in ASCEND:

(Please use blue or black ink)

Signature

PRINTED name

Today's date

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

Freepost RLJ-TKES-BURB, ASCEND, Richard Doll Building, University of Oxford, Old Road Campus, Headington, Oxford, OX3 7LF

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

Thank you very much



ASCEND

A Study of Cardiovascular Events in Diabetes



ASCEND Document Ref. A796-0673

ASCEND
Clinical Trial Service Unit (CTSU)
Richard Doll Building
University of Oxford
Old Road Campus
Headington
Oxford
OX3 7LF
Office telephone: 01865 743888
Office fax: 01865 743001
Freephone: 0800 585323
E-mail: ascend@ctsu.ox.ac.uk
Website: www.ctsu.ox.ac.uk/ascend

Mr Maurice Sigwood
13 Hoggens Road
Hogford
Hogwoodshire
H35 5PG

28 November 2006

Dear Mr Sigwood,

ASCEND: A Study of Cardiovascular Events in Diabetes

It is now about 2 months since you provisionally agreed to take part in ASCEND and received a box of study treatment. We would now like to know whether you are happy to continue into the long-term part of the ASCEND study. You may remember that 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 do not already have diagnosed circulatory problems.

On the back of this letter is a brief questionnaire which we would like you to complete and sign. Then please return it in the enclosed Freepost envelope. If you have any questions regarding the study you may telephone us or one of the other ASCEND staff on Freephone 0800 585323. Alternatively, you may wish to discuss matters with your GP or diabetes nurse before deciding whether to continue.

We hope you will decide to continue in ASCEND. If you do, then we shall send a new pack of study treatment as soon as we have received this completed form back from you. Subsequently, you will be sent a brief questionnaire to complete every six months and new supplies of study treatment. Alternatively, if you do not want to participate then please indicate this on the form and return it in the Freepost envelope provided.

Yours sincerely

Dr Jane Armitage

Dr Louise Bowman

Study Coordinators

On behalf of Dr JohnSmith, Hogford Acute Hospitals NHS Trust

Enc. FREEPOST envelope



ASCEND: Randomisation Questionnaire

INSTRUCTIONS FOR COMPLETION

Please complete the questionnaire in BLOCK CAPITALS using blue or black ink.

Please place a cross in the appropriate box, e.g. Yes No

(If you make a mistake, fill the entire box and mark the correct box, e.g. Yes No)

OR write clearly in the appropriate boxes, e.g. / /

1. Contact and GP Details

Please check that the contact details for you and your GP are correct. If not, then please call Freefone 0800 585323 and provide the correct information. Please quote the reference number from the covering letter on the front of this questionnaire.

Your details:

Mr Maurice Sigwood
13 Hogpens Road
Hogford
Hogwoodshire
HG5 5PG
09454 338993 (day); 09454 338993 (home)

GP details:

Dr GP Jones
55 Selwinton Road
Hogford
Hogwoodshire
HG5 8GP

2. Continuing in ASCEND

Are you willing to continue taking study tablets and capsules in ASCEND for the next 5 years? Yes No

If you answered YES, then please complete ALL the remaining sections of this questionnaire, sign and date the form, and return it in the FREEPOST envelope provided.

If you answered NO, then return the questionnaire in the FREEPOST envelope provided (but do not complete the remaining sections).

3. About Your ASCEND Medication

Please indicate how regularly you have taken your ASCEND medication since you received it.

	White Tablets (capsules or placebo), (one or other natural salt)	Brown Capsules	
Every day	<input type="checkbox"/>	<input type="checkbox"/>	Please cross ONE box only in EACH column
Most days	<input type="checkbox"/>	<input type="checkbox"/>	
Only occasionally	<input type="checkbox"/>	<input type="checkbox"/>	
Never	<input type="checkbox"/>	<input type="checkbox"/>	

4. About Your Diabetes

- 4.1 What year was your diabetes diagnosed?
- 4.2 Do you inject INSULIN for your diabetes? Yes No
- 4.3 If Yes, did you start insulin within one year of having diabetes? Yes No
- 4.4 Are you known to have diabetes changes at the back of the eye? Yes No
- 4.5 If Yes, have you ever had laser treatment to the eye for this? Yes No
- 4.6 Do you take treatment for high blood pressure or hypertension? Yes No

Need help completing this form? Please call Freefone 0800 585323

5. Confirming Your Medical History

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

- a) Heart attack Yes No
- b) Angina (chest pain from the heart) Yes No
- c) Stroke or ministroke (sometimes called TIA) Yes No
- d) Coronary artery bypass operation (CABG or "cabbage") Yes No
- e) Coronary angioplasty ("balloon", "stent" insertion or PTCA) Yes No
- f) Other arterial surgery or angioplasty (e.g. leg bypass) (Do not include angiogram) Yes No

Please cross
ONE box only
for each
question

R-281106

If Yes, please specify:

- g) Liver disease (active or chronic, or cirrhosis) Yes No

If Yes, please specify:

- h) Cancer within the last 5 years (e.g. skin, breast, lung, bowel etc) Yes No

If Yes, please give the type of cancer:

- i) Other serious illness Yes No

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 No
- b) Bleeding from the stomach or bowel? Yes No

6. About You

6.1 Please give your date of birth: / /

6.2 Which best describes your ethnic origin?

- White Black: African/Caribbean
- Indian, Pakistani or Bangladeshi Other
- Please cross ONE box only

6.3 Please provide your weight in light indoor clothes without shoes (round to nearest whole number). kgs OR stones & lbs

6.4 Please provide your standing height without shoes (round to nearest whole number). cms OR feet & inches

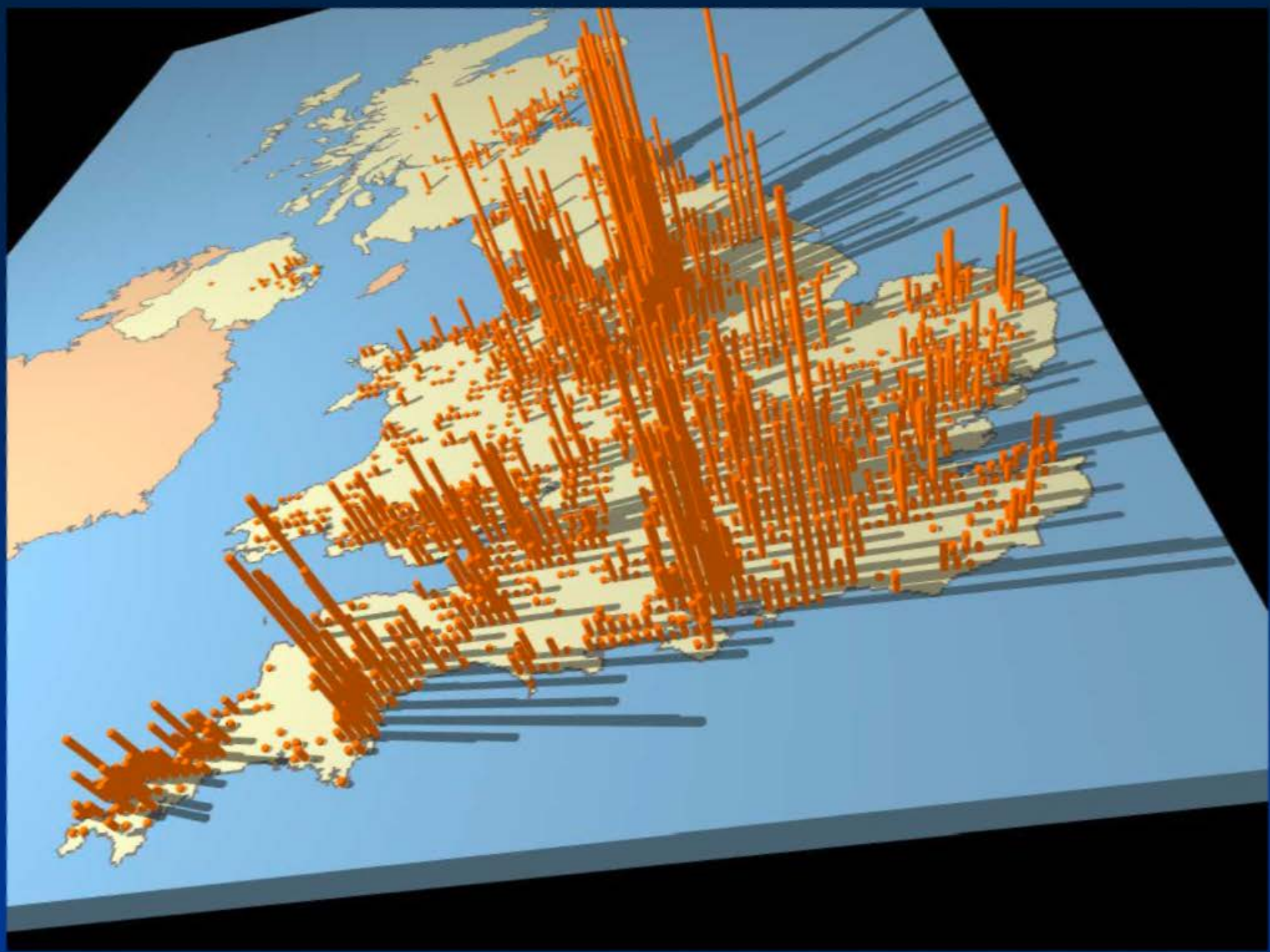
6.5 Do you smoke cigarettes regularly (i.e. on most days)? Yes No If Yes, give approximate number smoked per day:

6.6 If No, have you ever smoked regularly? Yes No If Yes, give the age you stopped: years

ASCEND: recruitment completed July 2011

	Centrally-held Register	GP practices	Others *	Total
Invitations sent	300,188	120,875	2223	423,286
Patients enter Run-in	16,104	9,741	635	26,480
Patients randomised	9013 (3.0%)	6037 (5.0%)	430 (19%)	15,480 (3.7%)

* HPS follow up/Self/friends/Hospital referral



Follow-up by mail

- Follow-up questionnaires sent 6 monthly:
 - serious adverse events
 - significant bleeding episodes
 - study treatment compliance
 - non-study treatments of interest
- Treatment packs mailed at appropriate intervals
- Central registries (death, cancer, MI, cardiac interventions, hospital admissions)
- 24 hour freefone telephone service

ASCEND: Follow-up Questionnaire

INSTRUCTIONS FOR COMPLETION

Please complete the questionnaire in BLOCK CAPITALS using blue or black ink.

Please place a cross in the appropriate box, e.g. Yes No

(If you make a mistake, fill the entire box and mark the correct box, e.g. Yes No)

OR write clearly in the appropriate boxes, e.g.

1. Contact and GP Details

Please check that these contact details are still correct. If not, then please telephone 0800 585323 and provide the correct information. Please quote the reference number from the covering letter on the front of this questionnaire.

Your details:

Mr Thomas White
24 Raspberry Road
Gardentown
Gardenshire
GA3 5TR
01234-987654

Alternative contact:

GP details:

Dr SC Black
The Surgery
23 Strawberry Street
Gardentown
Gardenshire
GA3 5RT
01234-654321

2. ASCEND Medication

2.1. Please indicate how regularly you have taken your ASCEND medication during the last 6 months.

	White Tablets (aspirin/placebo)	Brown Capsules (one or other natural oil)	
Every day	<input type="checkbox"/>	<input type="checkbox"/>	Please cross ONE box only in each column
Most days	<input type="checkbox"/>	<input type="checkbox"/>	
Only occasionally	<input type="checkbox"/>	<input type="checkbox"/>	
Never	<input type="checkbox"/>	<input type="checkbox"/>	

2.2. Are you willing to continue taking the white (aspirin/placebo) ASCEND tablets?

Yes No

If No, please tell us why:

2.3. Are you willing to continue taking the browns (one or other natural oil) ASCEND capsules?

Yes No

If No, please tell us why:

3. Other Current Medication

3.1. Do you currently take any of the following regularly (i.e. more than one day per week)?

a) Warfarin (Marevan), Acenocoumarol (Nicoumalone, Sirtrome) or Phenindione	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Please cross ONE box only for each question
b) Aspirin, prescribed or over-the-counter (e.g. Anadin, Caprin, Disprin, Imazin, PostM). Do not include your ASCEND study tablets.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
c) Clopidogrel (Plavix)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
d) Dipyridamol (Persantin, Persantin Retard) or Acasantin Retard)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

Need help completing this form? Please call Freephone 0800 585323

4. Medical Events

4.1. Since completing your last questionnaire on: [date] have you had ANY of the following? (If Yes, please give the date and the name and town of the hospital you attended). Please note there is extra space overleaf to list second occurrences of any of the medical events listed below.

a) Heart attack	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Name and town of hospital attended	<input type="text" value=""/>				
b) Admission to hospital with angina or any chest pains	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Name and town of hospital attended	<input type="text" value=""/>				
c) Stroke	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Name and town of hospital attended	<input type="text" value=""/>				
d) Ministroke (sometimes called TIA)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Name and town of hospital attended	<input type="text" value=""/>				
e) Coronary artery bypass operation (CABG or "cabbage")	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Name and town of hospital attended	<input type="text" value=""/>				
f) Coronary angioplasty ("balloon", "stent" insertion or PTCA)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Name and town of hospital attended	<input type="text" value=""/>				
g) Other arterial surgery or angioplasty (e.g. leg bypass)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Name and town of hospital attended	<input type="text" value=""/>				
h) Cancer (e.g. skin, breast, lung, bowel etc)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Type of cancer:	<input type="text" value=""/>				
Name and town of hospital attended	<input type="text" value=""/>				
i) Bleeding for which you saw a doctor (e.g. serious nose bleed, bleeding in the eye) Do not include bleeding as a result of an accident.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Site in body of bleeding:	<input type="text" value=""/>				
Were you admitted to hospital?	Yes <input type="checkbox"/>	No <input type="checkbox"/>			
Name and town of hospital attended	<input type="text" value=""/>				

Need help completing this form? Please call Freephone 0800 585323

5. Other Serious Illnesses or Hospital Admissions

5.1 Since completing your last questionnaire on _____ have you had ANY other serious illness or admission to hospital (e.g. pneumonia, day surgery, laser treatment to the eye)? Please give details of the illness or surgery, the date, and the name and town of the hospital you attended. (Please note you can also record second occurrences of any of the medical events listed in Section 4).

Details of illness or admission	<input type="text"/>
Name and town of hospital attended	<input type="text"/>
Date:	<input type="text"/> / <input type="text"/> / <input type="text"/>
Details of illness or admission	<input type="text"/>
Name and town of hospital attended	<input type="text"/>
Date:	<input type="text"/> / <input type="text"/> / <input type="text"/>
Details of illness or admission	<input type="text"/>
Name and town of hospital attended	<input type="text"/>
Date:	<input type="text"/> / <input type="text"/> / <input type="text"/>
Details of illness or admission	<input type="text"/>
Name and town of hospital attended	<input type="text"/>
Date:	<input type="text"/> / <input type="text"/> / <input type="text"/>

6. Personal Details

6.1 Please give your date of birth:

/ /

Thank you for completing the questionnaire.
Please SIGN and DATE the form below using blue or black ink.

Signature

& PRINTED name

Today's date:

/ /

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 FREEPHONE: 0800 585323 (preferably during office hours 9 am – 5 pm, Monday to Friday)

Thank you for your continued participation in ASCEND



ASCEND

A Study of Cardiovascular Events IN Diabetes



ASCEND Document Ref. A777-7772

Mr Thomas White
24 Raspberry Road
Gardentown
Gardenshire
GA3 5TR

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

Office telephone: 01865 404888
Office fax: 01865 404871
Freephone: 0800 585323
e-mail: ascend@trial.uo.ac.uk
Website: www.trials.uo.ac.uk/ascend

Dear Mr White,

ASCEND: A Study of Cardiovascular Events IN Diabetes

Thank you for your continued participation in ASCEND and your commitment to research into diabetes. On the back of this letter is a simple questionnaire similar to earlier ones you have returned. We would be grateful if you would complete and return it promptly in the Freepost envelope enclosed. We cannot emphasise enough how important it is that we receive this information regularly from each of the participants in ASCEND. We shall be sending you a new supply of study treatment automatically when it is required.

Please let us know if you have any questions or need help completing the questionnaire, by telephoning Freephone: 0800 585323.

Thank you for your continued support of ASCEND, and for being prepared to complete regular questionnaires. We are grateful for your help with finding ways of preventing the complications of diabetes.

Yours sincerely

Dr Jane Armitage

Dr Louise Bowman

Study Coordinators

On behalf of [local collaborator]

Enc: FREEPOST envelope



HIMALAYA

The newsletter of the ASCEND Study

Winter 2010 - Number 8



Welcome to the eighth edition of HIMALAYA - the newsletter of the ASCEND study. Thank you very much for your interest and participation in the ASCEND study so far. If you have not received HIMALAYA before, we hope this newsletter will educate and entertain you, and tell you more about the study that you are playing such a vital role in. If you have, then read on and find out what we have been up to since the last issue. The picture opposite shows Mt. Manaslu, located in the Mansiri Himal, part of the Nepalese Himalayas, which means "Mountains of the Spirit", and it is the eighth highest mountain in the world.



WE HAVE REACHED 12,000 PARTICIPANTS!

People from all over the UK are participating in ASCEND. We collect data on everyone who participates and here are some of the characteristics of the people taking part:

- 62% are men and 38% are women;
- 93% of people have "type 2" diabetes;
- average age is about 62 years;
- participants have had diabetes for an average of 10 years before entering the study;
- about 1 in 3 participants take insulin.



HOW DO I GET THE TABLETS OUT OF THE PACKS?

We realize that some of you have difficulty getting the study treatments out of the packaging. Our packaging has to meet "The Medicines (Child Safety) Regulations 2003" which require medicinal products containing aspirin to be packaged in child-resistant containers. The packaging technology is currently under review due to the problems encountered and we will let you know if there are any changes.

- 1 First remove the brown capsule. Apply moderate pressure towards the end of the capsule nearest the spine of the blister card.
- 2 Then peel back the foil and remove the brown capsule.
- 3 Continue to peel away the foil towards the edge of the blister card until the white tablet is partially revealed.
- 4 Finally, if should now be possible to push out the white tablet.

Where can people find out more?
visit the ASCEND website: www.ctsu.ox.ac.uk/ascend

They can: call a member of the study team: (Freephone) 0800 585323

THE ASCEND TEAM

In each issue of HIMALAYA we hope to introduce you to different members of the ASCEND team. This time we would like to introduce you to the faces behind the voices you first hear when you ring us. The three people in this picture (Jill Crowther, Angela Radley and Olivia Machin, from left to right) are the team who take the day-to-day phone calls for ASCEND. They have been responsible for answering many thousands of telephone calls over the years, fielding your questions and, when required, transferring calls to the relevant people when you've needed advice from a study doctor, nurse or administrator. We could call them the gateway to ASCEND; without whom the support network would rapidly grind to a halt.



ASPIRIN AND CANCER

You might have read or heard the recent news stories about the effect of aspirin on cancer. This is indeed interesting news, but as yet the answer is not clear. The published studies have not been able to weigh the relative benefits of possible cancer prevention against the risk of bleeding with long-term aspirin use. In particular, the recent publications have addressed this question in people with diabetes. It is noting that cancer was not the focus of any study included in the recent reports, which is included in the effects seen are chance. It is possible that the effects seen are chance. It is not clear how this might work. This is the focus of ongoing research. ASCEND is particularly examining the risks versus the benefits of aspirin (and of omega-3 fish oils) in diabetes, and we will also assess the effects of aspirin to prevent cancer and the widespread use of aspirin to prevent cancer and this is not generally being recommended by doctors or in the treatment guidelines. ASCEND will provide good evidence on which to make these decisions and we have no plans to change the study as a result of the recent reports.

It is important that you send in your completed questionnaires, even if you are no longer taking the study treatments since missing information can lead to unreliable results. We hope that the study treatments will reduce aspirin problems, but we also know that aspirin can slightly increase the risk of bleeding. One critical question ASCEND hopes to answer is "do the benefits of reducing circulatory problems outweigh the increased risk of bleeding?" Blood tests will not be able to tell us this; only careful follow-up of two large groups of people who only differ in whether they are taking aspirin or not (in words, you!) can. For ASCEND to be successful, as many participants as possible to take the treatments, and to complete their tests so we know how you are getting on.

DO YOU KNOW IF THE TABLETS ARE HAVING AN EFFECT?

ASCEND participants put questionnaires each day, and not do this if the treatments are not working. Sometimes you are no longer taking the study treatments since missing information can lead to unreliable results. We hope that the study treatments will reduce aspirin problems, but we also know that aspirin can slightly increase the risk of bleeding. One critical question ASCEND hopes to answer is "do the benefits of reducing circulatory problems outweigh the increased risk of bleeding?" Blood tests will not be able to tell us this; only careful follow-up of two large groups of people who only differ in whether they are taking aspirin or not (in words, you!) can. For ASCEND to be successful, as many participants as possible to take the treatments, and to complete their tests so we know how you are getting on.



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Summary of experience in ASCEND

- Successful recruitment of 15000 trial participants by mail using centrally-held and GP databases
- Streamlined trial design, simple CRFs completed by participants – no study clinics
- Follow-up is on-going, results anticipated 2017
- Results relevant to 350 million people worldwide with diabetes



The evolution of diabetes

