



ASCEND

A Study of Cardiovascular Events in Diabetes



ASCEND Document Ref. A765-4321

ASCEND
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12 August 2011

Dear Mr White,

ASCEND: A Study of Cardiovascular Events iN Dibetes

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 Freefone 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

Professor Jane Armitage

Dr Louise Bowman

Study Coordinators

On behalf of Dr Jack Black, Gardentown NHS Trust

Enc: FREEPOST envelope

Pt ID: A123-4567

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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. / /
Day Month Year

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 Thomas White
24 Raspberry Road
Gardentown
Gardenshire
GA3 5TR

GP details:

Dr AB Brown
The Medical Centre
Strawberry Field
Gardentown
Gardenshire
GA3 9ZZ
01234 543210

+

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

4. About Your Diabetes

- 4.1 What year was your diabetes diagnosed?
- 4.2 Do you use INSULIN (injections or via pump) 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 *Please cross ONE box only for each question*
- 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) Yes No

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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: / /
Day Month Year



6.2 Which best describes your ethnic origin?

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

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

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:

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: / /

Day Month Year

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 RLUJ-TKES-SURB, 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 **FREEFONE: 0800 585323** (preferably during office hours 9 am - 5 pm, Monday to Friday)

Thank you very much