

Blood and urine sample for immediate and future medical research

Thank you for continuing to take part in ASCEND (A Study of Cardiovascular Events in Diabetes). ASCEND has finished recruitment and there are now 15,480 people with diabetes taking part. With your help, we hope to be able to answer the important questions about whether aspirin and/or omega-3 fatty acids prevent heart disease and strokes in people with diabetes who have not had any circulatory problems.

We would now like you to consider whether you would be happy to provide an **optional** extra blood sample and urine specimen, both for immediate measurements and for long-term storage. The enclosed sampling kit is to be used to collect the blood sample (about two teaspoonfuls) and urine specimen at your local general practice. These samples will then be sent to the coordinating centre laboratory where the measurements would be made. We would also ask for an updated measurement of your weight and record the time of your last dose of study treatment. However, if you would prefer not to provide these samples you can still continue in ASCEND and this would not affect your taking part.

Please take time to read the following information carefully and discuss it with your GP, friends or relatives if you wish. If there is anything that is not clear, or if you would like more information, please do not hesitate to telephone the ASCEND Freephone number (0800 585323) and speak to a study nurse or doctor.

Blood and urine measurements

At the beginning of the study, you provided us with a blood and urine sample which was used to look at factors known to affect the risk of heart problems and diabetes complications (including blood sugar control, cholesterol levels and kidney function). These baseline measurements will allow us to see whether the effects of the treatments being used in the study vary between different types of people taking part. We have also stored some samples to be able to look at other

measures in future. We would now like to repeat those tests to see whether the study treatments are having any effect on these factors. We will write to your GP with the results so that any relevant action could be taken. In addition, we plan to look at some other effects of the study treatments.

What are the risks of allowing my samples to be stored long-term?

There are no risks at all to you. The study coordinators in Oxford University will be the only people who are able to link test results with individual participants, and the data will be held confidentially within a secure computer system. The information from any future analyses of your samples will not be provided to you, your doctors, or anybody else. In particular, having these samples stored and subsequently tested would not affect your ability to obtain insurance.

What if I don't wish to allow my blood or urine samples to be stored long-term?

If you are happy to provide a blood and urine sample for immediate measurements but do not wish the samples to be stored for future analyses then please indicate this on the enclosed consent form by crossing "Yes" or "No" as appropriate against the different sections.

What should I do next?

If, after reading this leaflet, you feel that you would be willing to provide a blood and urine sample then please complete and sign the enclosed consent form (placing a cross next to each of the statements to which you agree or disagree). You will then need to make an appointment for a blood test at your local surgery, take the sampling kit, consent form and Freepost envelope and ask the practice nurse to collect the blood sample and take a measurement of your weight, record the time of the last dose of study medication and your current medication list. The practice nurse will then send the samples and completed consent form to the ASCEND coordinating centre in the Freepost envelope provided.

If you or the practice nurse have any further questions about this, please contact the ASCEND coordinating centre on the Freefone 0800 585323

THANK YOU FOR YOUR HELP



ASCEND

A Study of Cardiovascular Events in Diabetes



A randomised study of aspirin and of natural oils
for the primary prevention of cardiovascular
events in diabetes

INFORMATION ABOUT OPTIONAL BLOOD & URINE SAMPLING

This leaflet contains important information about providing an optional blood and urine sample for the ASCEND study. Please read all the information contained in this leaflet carefully. If you have any further questions about providing a blood and urine sample, you can speak to an ASCEND study nurse or doctor on Freefone 0800 585323.

Please keep this information sheet for your own records.

THANK YOU FOR YOUR HELP

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