



ASCEND

A Study of Cardiovascular Events in Diabetes



What will happen to the information that is collected?

Data from the tests will be stored securely and analysed. We will ensure that any results published in future will not identify you or be traceable to you.

Who is running and who is funding this research?

The ASCEND study, including the assessment of cognitive function, is co-ordinated by Professor Jane Armitage and Dr Louise Bowman at the Clinical Trial Service Unit, University of Oxford. ASCEND is funded by the British Heart Foundation. The study aspirin or placebo is provided by Bayer Healthcare AG and the omega-3 fatty acid capsule or placebo is provided by Mylan NV (formerly Abbott Products Operations AG) with additional funding from both companies to cover drug packaging. The additional costs of measuring cognitive function in ASCEND are provided by Alzheimer's Research UK.

How do I find out more about this?

More information about the cognitive function assessment can be found on the study website: www.ctsuo.ox.ac.uk/ascend.

If you have any questions about this, or any other part of the study, please contact the ASCEND coordinating centre.

By phone: Freefone service: 0800 585 323
(from outside UK: +44 1865 765615)

By e-mail: ascend@ctsuo.ox.ac.uk

By post: ASCEND
Clinical Trial Service Unit (CTSU)
Richard Doll Building
Roosevelt Drive,
OXFORD, OX3 7LF

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

INFORMATION ABOUT AN OPTIONAL COGNITIVE FUNCTION ASSESSMENT

This leaflet contains important information about an optional cognitive function assessment for the ASCEND study. Please read all the information contained in this leaflet carefully. If you have any further questions about this 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

Co-ordinated by:

Clinical Trial Service Unit, University of Oxford
E-mail: ascend@ctsuo.ox.ac.uk
Website: www.ctsuo.ox.ac.uk/ascend



Thank you for your valuable contribution to the ASCEND study. As you know, ASCEND aims to find out whether taking an aspirin tablet, and/or an omega-3 fatty acid (fish oil) supplement, can safely reduce the risk of heart or circulatory problems (such as heart attacks and strokes) among people who have diabetes, but who did not have known circulatory problems when they started the study. We would also like to find out whether these treatments have any effects on cognitive function (memory and brain power).

It is known that there is a link between dementia and diseases of the heart or circulation. Risk factors for circulatory diseases such as smoking, diabetes and high blood pressure are also more common in people who develop dementia. However, it is not known whether treatments such as aspirin, which can help to protect against heart attacks and strokes, might affect memory and brain power and affect the risk of developing dementia.

Why have I been chosen to take part?

We are inviting all ASCEND participants who continue to complete their follow-up forms to take part in this **optional** cognitive function assessment.

Do I need to take part?

No, it is entirely voluntary. You would not be given any results from the test and it will not affect your other involvement in ASCEND.

What would happen if I agree to take part?

If you complete paper ASCEND follow-up forms, a member of the ASCEND team will call you to do a telephone cognitive function assessment. You will be asked 5 questions about your mood followed by 16 short questions to test different mental processes (e.g. memory, reason and logic). At the end you will be asked about your level of education. You do not need to answer this question if you prefer not to. The questions take about 10-15 minutes to complete. If you receive a call at a time which is not convenient but are willing to do the test, you will be able to reschedule the cognitive function assessment.

If you complete your ASCEND follow-up forms online, you will be sent an e-mail. This will contain an electronic link to a secure online cognitive function test. Clicking on the link will take you to a screen that explains what you are being asked to do and gives you the option to continue, if you are happy to do so. The online test involves answering some questions about your mood and then doing some games and puzzles that assess your memory, reasoning and thinking and reaction speed.

There are five questions to answer about your mood followed by six tests to complete. At the end you will be asked about your level of education. You do not need to answer this question if you prefer not to. The questions and tests take about 20 minutes to complete. You do not have to finish all of them at once. You can choose when you want to do them and how many you complete at one time. If you choose to take a break in the middle of a test, it will be counted as finished and, when you restart you will be taken to the next test. The tests are self-explanatory; each starts with a description, followed by instructions about what you need to do and an example of the type of exercise.

If possible please complete the mood questions and memory tests within two weeks of receiving the e-mail with the electronic link.

If you do not want to be contacted about the cognitive function test please let the study staff know using the contact details at the end of this leaflet.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks of taking part. The results of the test will be stored securely in the study computer. You will not receive your own individual test results.

What are the possible benefits of taking part?

There are no benefits to you of taking part. However, these tests will allow a better understanding of any effects of aspirin and/or omega-3 fatty acids on cognitive function.