

ASCEND-EYE

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An invitation to take part in the ASCEND-EYE sub-study

We are writing to tell you about a new voluntary part of ASCEND known as ASCEND-EYE. The purpose of ASCEND-EYE is to see whether aspirin and fish oils have any effect on various eye diseases.

Before you agree to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. You are free to decide whether or not to take part in this sub-study. If you choose not to take part, the standard of care you are given by your own doctors will not be affected.

Diabetes and the eye

Having diabetes can affect your eyes and your ability to see. The most common and serious problem is diabetic retinopathy which is caused by damage to the delicate network of blood vessels at the back of the eye known as the retina. In severe disease, disorganised growth of new blood vessels causes bleeding and scarring which may result in loss of sight. Fortunately diabetic retinopathy can be prevented and treated if it is caught at an early stage. This is why the NHS invites people with diabetes to attend regular eye screening examinations. As part of this examination photographs are taken of the back of the eyes.

Aspirin and omega-3 fatty acids on diabetic retinopathy

Studies from the 1960s first suggested that tiny blood clots blocking blood vessels in the retina could start a chain of events that results in diabetic retinopathy. Because aspirin is known to reduce the risk of blood clots elsewhere in the body, doctors thought that it might be a useful treatment for diabetic retinopathy, but there were also concerns that it might cause bleeding in the eye. Two well-conducted but small clinical trials sought to investigate this further. One found that aspirin neither harms nor protects against diabetic retinopathy, but they only included people who were already known to have moderate disease. The other found that aspirin prevented early changes in the back of the eye in those without existing disease. However, it wasn't clear whether aspirin would slow the progression of diabetic retinopathy in the long-term because the number of people who took part in the study was too small and the follow-up period was too short to assess this reliably. Given the large number of people taking part in the main ASCEND trial who have now been taking aspirin or placebo (dummy aspirin) for several years, we have the chance to assess whether aspirin might help to protect against diabetic retinopathy.

The effects of omega-3 fish oils on diabetic retinopathy have never been explored before. It is possible that they might also have a beneficial effect but it is not known. ASCEND-EYE is well placed to find this out.

Ageing and the Eye

People often notice they see less well as they get older. For most people, these changes are caused by weakening of the muscles that help us to focus on objects of interest. This is why older people often need reading glasses. However, a small proportion of people have a condition called age-related macular degeneration. This is a leading cause of poor sight and blindness among older adults in the UK. In macular degeneration damage occurs in the area of the back of the eye which is responsible for central vision and seeing fine detail and colour. This damage can be serious – affecting the ability to recognise faces, drive a car or read and write. Having diabetes **is not** thought to increase the risk of age-related macular degeneration, but research suggests that both aspirin and omega-3 fish oils could play a role.

Aspirin and omega-3 fish oils on age-related macular degeneration

Doctors think that taking regular aspirin may improve age-related macular degeneration because of its effects on the circulation. The use of aspirin by those with age-related macular degeneration has been investigated in previous studies, but with inconsistent results. Because aspirin is so widely used by older people it is important to understand whether it is having an effect.

Studies of fish oils have also produced inconsistent findings on age-related macular degeneration. Some studies suggest that people who eat oily fish regularly or take fish oil supplements have less eye problems but high quality studies have not shown benefit from taking fish oil supplements in people who already knew they had the disease.

What does the ASCEND-EYE sub-study hope to answer?

ASCEND-EYE will find out if there are any beneficial or harmful effects of taking aspirin and/or omega-3 fish oils on diabetic retinopathy and age-related macular degeneration. It will also collect information about other eye problems that are commonly seen in people with diabetes such as cataracts.

What will taking part in ASCEND-EYE involve?

Taking part in ASCEND-EYE will involve filling in a detailed questionnaire about your sight and how any problems affect your day-to-day activities like reading and driving. The questionnaire will take about 20 minutes to complete.

Coordinating centre activities in the ASCEND-EYE sub-study

The ASCEND coordinators will be writing to GPs to ask about any bleeding in the eye that you may have reported to us during ASCEND trial. At the beginning of ASCEND you gave consent to allow information about your health to be collected from national registries. As part of ASCEND-EYE we will be collecting information from the NHS Diabetic Eye Screening service about any diabetic retinopathy that has been recorded. If you would prefer us not to do this, please telephone the ASCEND Freephone number (0800 585323) and ask to speak to one of the study team.

What you have to do to join the study

If you are happy to take part, please complete and return the enclosed questionnaire in the FREEPOST envelope to the coordinating centre at Oxford University's Clinical Trial Service Unit. You should also keep this information sheet.

Will my taking part in the ASCEND-EYE sub-study be kept confidential?

Yes - all information which is collected about you during the course of ASCEND-EYE will be kept strictly confidential and used only for medical research purposes and for routine regulatory and audit purposes.

Study organisation

The ASCEND-EYE study has been designed and is coordinated by Oxford University's Clinical Trial Service Unit. The study design has been reviewed and agreed by an independent Research Ethics Committee, which includes people from outside the medical profession.

Contact Information

If there is anything that is not clear, or if you would like more information, please telephone the ASCEND Freephone number (0800 585323) and ask to speak to a study nurse or doctor. A larger font version of the questionnaire can also be viewed on our website: www.ctsu.ox.ac.uk/ascend

Thank you very much for taking the time to read this information sheet