

The newsletter of the ASCEND Study

Winter 2012 – Number 11

Welcome to the eleventh edition of **HIMALAYA** – the newsletter of the ASCEND study. As always, thank you very much for your help and participation in the study so far. We hope this newsletter will inform and entertain you, and tell you more about the study in which you are playing such a vital role. Please read on and find out what we have been up to since the last issue.

Gasherbrum I, the picture on the right, located in the Karakoram region of the Himalayas, on the Pakistani-Chinese border, is the eleventh highest mountain in the world. It is one of the “eight-thousanders” at 8,080 metres high. The meaning of Gasherbrum is “beautiful mountain”. It is also known as “Hidden Peak” for its extreme remoteness.



Recent news about aspirin

Cancer: You may have heard recent reports that aspirin might reduce the risk of certain cancers. So far, the published studies have not been able to weigh any possible benefits of cancer prevention against the risks of bleeding with long-term aspirin use. The side effects of aspirin are well known to include a risk of bleeding (in the stomach and rarely in the brain), and this complication is more common in people with diabetes compared to those without. ASCEND will be the biggest trial to investigate whether aspirin reduces the risk of cancer, and whether it does so safely. These results — in addition to the evidence on cardiovascular disease — make ASCEND an incredibly valuable study.

Visual loss: A recent study looked at whether a visual problem called Age-related Macular Degeneration (AMD) was linked with whether people had previously taken aspirin or not. The results suggested that people who had AMD were more likely to have taken aspirin in the past, but this does not necessarily mean that AMD is caused by aspirin. Other studies have suggested that aspirin might actually help with certain visual problems. Along with providing very important information about whether it is a good idea to use aspirin to prevent heart disease and cancer, ASCEND will also help doctors to understand much more about whether aspirin is good or bad for the eyes in people with diabetes.

What ASCEND can add to benefit people with diabetes?

Nearly 350 million people worldwide have diabetes (with about 3 million in the UK). ASCEND is one of the largest randomised controlled trials among people with diabetes with 15,480 participants now being followed up. Even if ASCEND only shows there is a small benefit (or harm) with aspirin or omega-3 fish oils, this could translate into preventing many thousands of heart attacks, strokes or episodes of bleeding worldwide every year. This highlights why your involvement with this trial really will help many millions of diabetic people worldwide.

Why does ASCEND need to take so long?

We need to follow up all our participants for at least seven years because — like many modern medical treatments — the effects of the ASCEND study treatments may only be moderate. This means that it may take several years of treatment for a clear difference to appear (if there is one) between the

groups who are taking active treatments and the groups taking placebo (“dummy”) treatments. It is, therefore, very important for you and your fellow participants to continue in the study long enough for us to be able to detect any treatment effects.

Where can people find out more?

They can:



visit the ASCEND website: www.ctsuo.ox.ac.uk/ascend



call a member of the study team: (Freefone) 0800 585323

The ASCEND Team

The Laboratory Team

The Himalaya newsletter is a good opportunity to introduce you to the people working behind the scenes who make the ASCEND study possible. The photo on the right is the team working for the Wolfson Laboratory at the University of Oxford. These people do the measurements on the blood and urine samples that some of you have sent to us. The team is led by Dr Michael Hill who is an experienced scientist and laboratory manager. As well as the ASCEND samples they analyse and store samples from other large studies. They handle hundreds of thousands of samples each year.



What can you do to help people with diabetes?

We are very grateful to you for playing such a vital role in helping us try to improve the health of the millions of people around the world with diabetes. If you can, please continue to take the study medications. We would also encourage you to complete and return the blue follow-up questionnaires which you should receive about every 6 months, even if you are no longer taking the study medications. If a doctor starts you on one of the drugs mentioned on the follow-up form (Section 3.1), please do call on the Freefone number below to discuss it. If you have had any illness needing hospital admission, please let us know on the form in Sections 4 & 5 as this information will be very valuable to the trial. With your help, ASCEND will try to provide clear answers, and make a major contribution to the treatment of the 300 million people with diabetes in the world for many years to come. Thank you for your commitment and for your continued participation in this important health study.

Frequently Asked Questions (FAQs)

Q: If I have stopped taking the tablets or capsules why do I need to still complete questionnaires?

A: To get reliable results everyone who agreed to join ASCEND should be counted in the final analysis – whether or not they continued to take the pills. This may seem surprising but is very important. If people who stop the treatment are not included it may lead to the wrong conclusion because the groups being compared are no longer similar. By filling in the follow-up questionnaires, even if you are no longer taking the treatment, you are helping the study results to be more reliable.

Q: What if I am due to have an operation or procedure?

A: Please tell the team that you may be on aspirin. Depending on the type of operation, you may be asked to stop the ASCEND white tablets beforehand. Because aspirin can cause more bleeding during surgery it is very important to tell people that you are in ASCEND. If you are not sure what to do, please do call us on the Freefone number.

Q: Is it okay to restart the tablets or capsules after a break from them?

A: Yes, and it doesn't matter how long the break has been. Please call 0800 585323 if you need a new pack of medication. It is much better for the study that you restart, even if you haven't taken the study tablets or capsules for a while.

Q: How do I know if the study treatments are having effects?

A: ASCEND is trying to find out if aspirin and fish oils reduce the chances of a heart attack or stroke without causing too much bleeding. However, the tablets and capsules will not affect how you feel. It is not possible to know whether they are having an effect until the study is over.

Q: Will I be told at the end of the study which arm of the study I was on (aspirin or placebo & omega-3 fish oils or placebo)?

A: If you want to know you will be able to find out by telephoning the study. If your doctors need to know sooner because of an emergency, they can always find out by calling the Freefone number.



Freefone 0800 585323

ASCEND is coordinated by the *Clinical Trial Service Unit* of the *University of Oxford*



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