

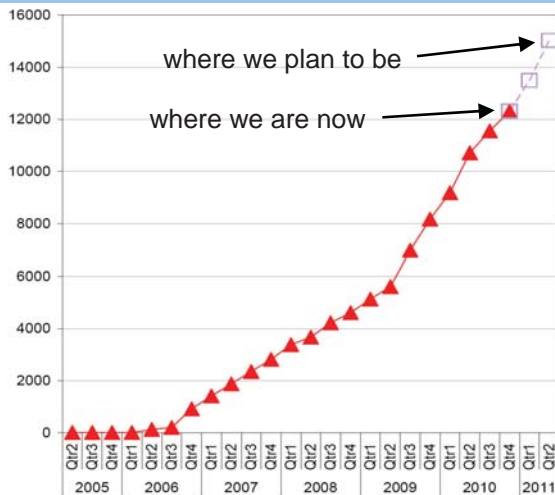
The newsletter of the ASCEND Study

Winter 2010 – Number 8

Welcome to the eighth edition of **HIMALAYA** – the newsletter of the ASCEND study. Thank you very much for your interest and participation in the ASCEND study so far. If you have not received **HIMALAYA** before, we hope this newsletter will educate and entertain you, and tell you more about the study that you are playing such a vital role in. If you have, then read on and find out what we have been up to since the last issue. The picture opposite shows *Mt. Manaslu*, located in the Mansiri Himal, part of the Nepalese Himalayas, which means "Mountain of the Spirit", and it is the eighth highest mountain in the world.



WE HAVE REACHED 12,000 PARTICIPANTS!







People from all over the UK are participating in ASCEND. We collect data on everyone who participates and here are some of the characteristics of the people taking part:

- 62% are men and 38% are women;
- 93% of people have "type 2" diabetes;
- average age is about 62 years;
- participants have had diabetes for an average of 10 years before entering the study;
- about 1 in 3 participants take insulin.

HOW DO I GET THE TABLETS OUT OF THE PACKS?

We realize that some of you have difficulty getting the study treatments out of the packaging. Our packaging has to meet "The Medicines (Child Safety) Regulations 2003" which require medicinal products containing aspirin to be packaged in child-resistant containers. The packaging technology is currently under review due to the problems encountered and we will let you know if there are any changes.

<p>1</p>  <p>First remove the brown capsule. Apply moderate pressure towards the end of the capsule nearest the spine of the blister card.</p>	<p>2</p>  <p>Then peel back the foil and remove the brown capsule.</p>	<p>3</p>  <p>Continue to peel away the foil towards the edge of the blister card until the white tablet is partially revealed.</p>	<p>4</p>  <p>Finally, it should now be possible to push out the white tablet.</p>
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Where can people find out more?

They can:



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



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

THE ASCEND TEAM

In each issue of **HIMALAYA** we hope to introduce you to different members of the ASCEND team. This time we would like to introduce you to the faces behind the voices you first hear when you ring us. The three people in this picture (Jill Crowther, Angela Radley and Olivia Machin, from left to right) are the team who take the day-to-day phone calls for ASCEND. They have been responsible for answering many thousands of telephone calls over the years, fielding your questions and, when required, transferring calls to the relevant people when you've needed advice from a study doctor, nurse or administrator. We could call them the gateway to ASCEND; without whom the support network would rapidly grind to a halt.



ASPIRIN AND CANCER

You might have read or heard the recent news stories about the effect of aspirin on cancer. This is indeed interesting news, but as yet the answer is not clear. The published studies have not been able to weigh the relative benefits of possible cancer prevention against the risk of bleeding with long-term aspirin therapy. In particular, the recent publications have not addressed this question in people with diabetes. It is worth noting that cancer was not the focus of any of the trials included in the recent reports, which makes it possible that the effects seen are chance findings. If aspirin does protect against cancer, it is

not clear how this might work. This is the focus of ongoing research. ASCEND is particularly examining the risks versus the benefits of aspirin (and of omega-3 fish oils) in diabetes, and we will also assess the effects of aspirin treatment on cancer. We do not think there is enough evidence to support the widespread use of aspirin to prevent cancer and this is not generally being recommended by doctors or in the treatment guidelines. ASCEND will provide good evidence on which to make these decisions and we have no plans to change the study as a result of the recent reports.

HOW DO YOU KNOW IF THE TABLETS ARE HAVING AN EFFECT?

We appreciate the effort ASCEND participants put into taking their study treatments each day, and completing the follow-up questionnaires. Sometimes we are asked how people can tell if the treatments are having any effect, since we do not do regular blood tests or see you in a clinic. Other participants tell us that they don't feel any different while taking study tablets. This is because the main outcomes of the ASCEND study are circulatory problems, like heart attacks and strokes. We do not expect the study treatments to have any significant impact on how you feel, or on blood results or on blood pressure, although this is not to say that they will not affect circulatory problems, and therefore your overall health. We know that we can collect reliable information from questionnaires and by telephone about how many participants have had



problems with their circulation. It is important that you send in your completed questionnaires, even if you are no longer taking the study treatments since missing information can lead to unreliable results.

We hope that the study treatments will reduce circulatory problems, but we also know that aspirin can slightly increase the risk of bleeding. One critical question ASCEND hopes to answer is "do the benefits of reducing circulatory problems outweigh the increased risk of bleeding?". Blood tests will not be able to tell us this; only careful follow-up of two large groups of people who only differ in whether they are taking aspirin or not (in other words, you!) can. For ASCEND to be successful, we need as many participants as possible to take their study treatments, and to complete their questionnaires so we know how you are getting on.



Freefone 0800 585323

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



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www.ctsu.ox.ac.uk/ascend