

ASCEND PLUS

A STUDY OF CARDIOVASCULAR EVENTS IN DIABETES

How can we protect people with type 2 diabetes from heart attacks, strokes and other health problems?

You are invited to join ASCEND PLUS, a clinical trial in people with type 2 diabetes.



You are invited to join a clinical trial called ASCEND PLUS which is coordinated by the Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU) at the University of Oxford.

This leaflet will tell you about the trial to help you decide if you are interested in taking part.

You can contact the ASCEND PLUS team using the contact details on the back page if you have questions.

What are clinical trials and why do they matter?

Clinical trials are the best way to find out how well medicines work. Clinical trial participants (usually patients with a particular condition or sometimes healthy volunteers) are asked to take either the trial treatment or the comparison treatment. The comparison treatment can be a placebo (which looks like the trial treatment but has no active drug in it). Medications prescribed in the UK – from anti-cancer drugs to COVID-19 vaccines – have been thoroughly tested in clinical trials.

“ I felt like I was in a very good position to contribute, and it felt like a useful, positive way that I could help.

- Harriet, clinical trial participant

CTSU has over 30 years of experience in leading clinical trials and other studies involving thousands of people; these trials have helped to improve the care of many thousands of patients across the world. These studies were only possible because people like you volunteered to take part.



What is this clinical trial about?

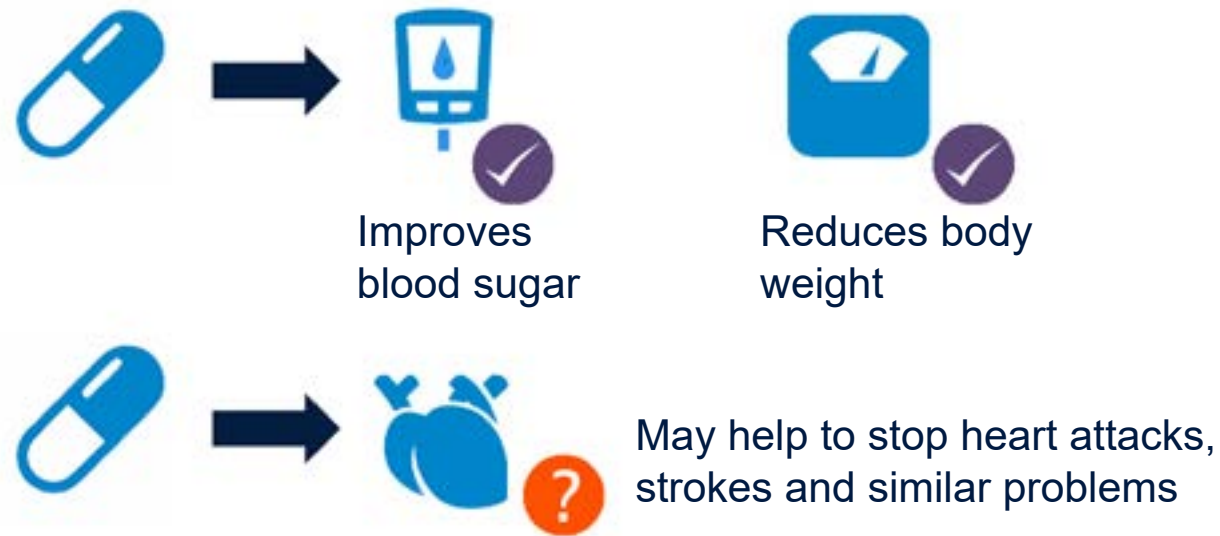
Having type 2 diabetes increases the risk of other major diseases, including heart attacks, strokes, kidney failure, blindness, dementia and lower limb amputation. University of Oxford researchers are working to identify more effective treatments that will help people with diabetes to reduce those risks.

ASCEND PLUS is testing a tablet medication called oral semaglutide, which helps to control blood sugar levels and lower body weight. It is approved for use in the UK as a treatment for type 2 diabetes. 'Oral' means that it is taken by mouth.

Medications which work in a similar way as oral semaglutide, are known to reduce the risk of heart and circulatory problems, such as heart attacks and strokes, for people who already have these conditions. However, oral semaglutide, and similar medications, are currently recommended only for people with diabetes who already have certain other medical conditions, and not many patients in the UK are prescribed them.

The aim of this study is to find out whether oral semaglutide can prevent heart and circulatory problems **in a broad range of people living with type 2 diabetes who have never had a heart attack or a stroke**. This would help doctors to know whether the treatment should be recommended more widely.

Oral semaglutide



Oral semaglutide could also potentially reduce the risk of people with type 2 diabetes developing other health problems related to diabetes, such as kidney disease and long-term memory problems including dementia. The ASCEND PLUS research team will also investigate this.

Why me?

People may be able to take part in ASCEND PLUS if they are at least 55 years old, have type 2 diabetes and have not had a heart attack or stroke in the past. A computer search of your health records suggested you may be able to take part in this trial.

Do I have to take part?

No, you do not have to take part in this study. **It is your decision.** But if you did help, many millions of people from around the world might benefit from this research in years to come.

What will I be asked to do if I take part?

The ASCEND PLUS researchers plan to recruit 20,000 volunteers. Half will get tablets containing semaglutide and half will get inactive placebo tablets (which look like the semaglutide tablets but have no active drug in them).

Which treatment you get is decided by chance using a computer program and you will not know if you are taking the active tablet or the placebo.

If you join the study, you will be asked to do the following:

- Take **one study tablet** each day for about five years, in addition to any other medication you take.
- Complete a questionnaire four times in the first six months, and then once every six months.

In total, this will be about 12 questionnaires spread over five years. Each one will take 20-40 minutes.

You can choose whether you complete these online yourself or with a research nurse by telephone or video call.

No additional clinic visits or travel are required to take part. The study medication will be posted to your address. However, if you have questions you can talk to a study nurse or doctor.



What are the benefits of taking part in this study?

Taking part in this trial might not help you. However, you will be helping doctors and scientists improve treatment for people with type 2 diabetes. If successful, results from this study might help to prevent many thousands of heart attacks, strokes and heart artery stenting ('balloon') and bypass procedures around the world.

Are there any risks?

Most treatments have side effects, which some people may experience, and others may not. Oral semaglutide is already approved for treating some patients with type 2 diabetes. About one in 10 people who take semaglutide experience nausea (feeling sick), vomiting, or diarrhoea. If severe, these symptoms can lead to dehydration. These problems usually happen soon after starting the medication (or when the dose is increased) and go away with time.

You can stop taking the study medication at any time if you want.

I'd like to take part - what should I do next?

Please return the reply form in the pre-paid envelope if you are interested in hearing more about the study. We will send you a full participant information leaflet and details of how you can join the study. If you do not wish to take part, you don't need to do anything. You may receive a further letter about the study but you don't need to reply.

You can also learn more about the study, and download the full participant information leaflet, on our website (www.ascend-plus-trial.org). You can contact the ASCEND PLUS team if you have any questions (see back page for contact details).

This is your chance to make a difference. With 20,000 volunteers we could help improve the lives of the millions of people worldwide with type 2 diabetes. You could be one of these volunteers.

How was data about me processed to send me this invitation?

A computer search of your electronic medical record held by NHS Digital suggested you might be able to take part. The study invitation letter was produced, printed and mailed by Paragon Customer Communications Ltd who also handle patient letters for the NHS. Your name, address, and postcode were passed securely to Paragon Customer Communications Ltd who will not use this personal data for any other purpose and will delete the data within 30 days of sending this invitation letter.

Your details are not disclosed to the ASCEND PLUS team at the University of Oxford unless you send the reply form to them.

If you return the reply form to the ASCEND PLUS team, this includes your name and the details you add, such as your telephone number and e-mail address. The bar code in the reply form contains a unique identifier which the ASCEND PLUS team can use to find out your details from NHS Digital. The ASCEND PLUS team also securely sends this code to NHS Digital who provide your name, address, sex (as registered with the NHS), date of birth, NHS number and GP surgery details.

This process has approval (known as 'favourable opinion') from the South Central - Oxford B Research Ethics Committee, and support from the Health Research Authority (HRA) following advice from the Confidentiality Advisory Group (an independent body which provides expert advice on the use of confidential patient information).

You can choose whether the NHS uses your data for research and planning at <https://www.nhs.uk/your-nhs-data-matters/>.

You can find out more about how data about you has been processed and your rights, by visiting the the NHS Digital website (<https://digital.nhs.uk/ascend-plus>). If you do not want to hear about the ASCEND PLUS study again, you can tell NHS Digital by using this website.

Contact Information

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Please contact the ASCEND PLUS office
if you would like to receive this document
in another format

IRAS: 1004252

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