

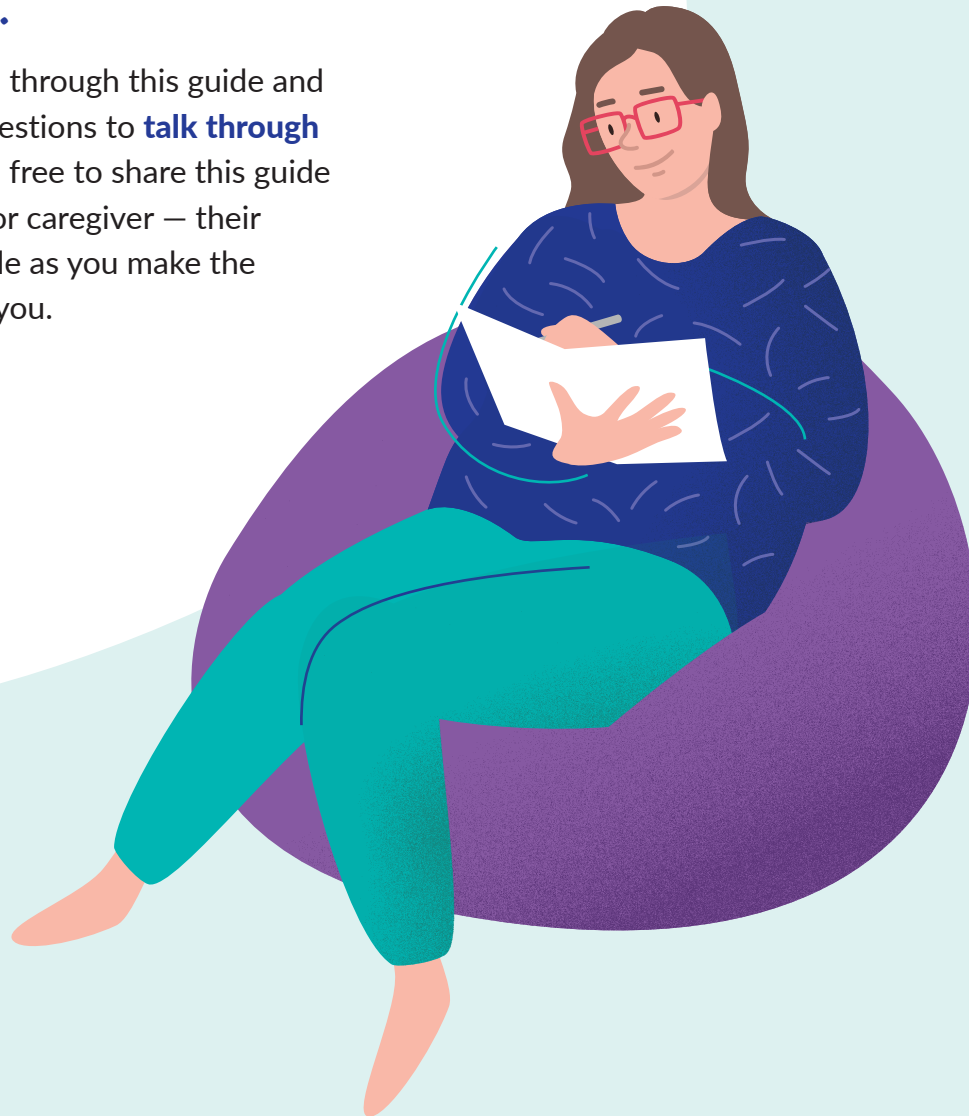


Flowing forward together

We understand that taking part in a clinical study is a big decision and so we want to give you all the information you need to feel confident and informed.

Thank you for your interest in AZURE-OUTCOMES, a clinical study for people with *atherosclerotic cardiovascular disease (ASCVD)*, or at risk for ASCVD-related health problems.

Take your time to read through this guide and make a note of any questions to **talk through with your doctor**. Feel free to share this guide with your loved ones or caregiver — their support can be valuable as you make the choice that's right for you.



What is a clinical study?

Clinical studies (sometimes called “clinical trials”) are a type of **research**. With the help of volunteer participants with specific health conditions, they look to find potential new treatments.

A clinical study is part of a careful process to understand how a potential medicine works, how safe and effective it is, and how it may compare against existing treatments.

Each clinical study is reviewed and monitored by a group of specialists to help protect everyone involved. We’ve also listened to feedback from other patients, to make this study as easy as possible to take part in.

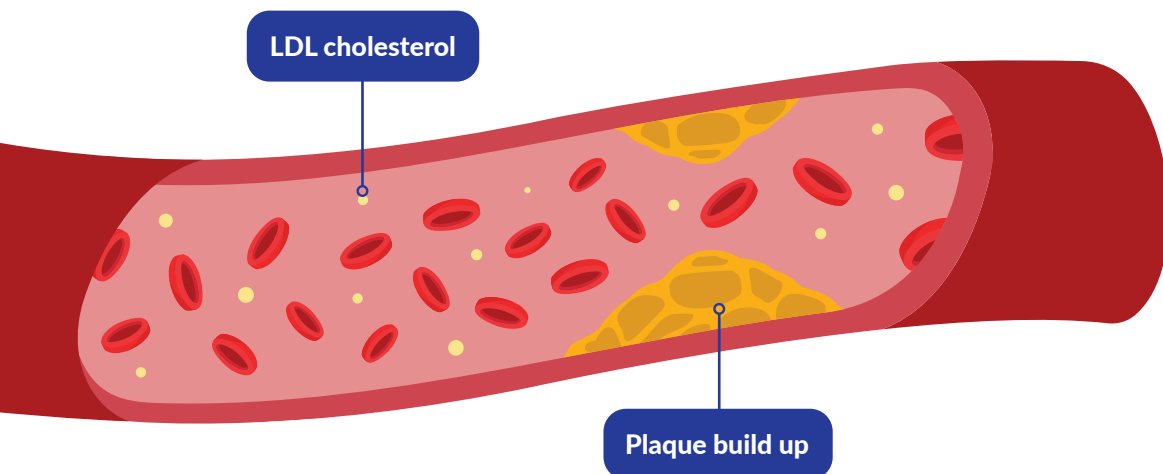
But remember, it’s *always your choice* whether to take part. You can choose not to join, or leave at any time after discussing it with the study doctor, and it will not affect your regular care in any way. Taking part will not cost you anything. However, if you have health insurance, it may be worth discussing the study with your provider.



What is ASCVD?

ASCVD is a group of conditions caused by the buildup of fatty deposits (**plaque**) in your blood vessels. Over time, this can block blood vessels, limiting blood flow to important organs and to the limbs, putting **extra strain on your heart**. This can increase the risk of cardiovascular problems, and in some cases, can lead to serious events like a heart attack or stroke.

One of the biggest contributors to the buildup of plaque is **low-density lipoprotein (LDL) cholesterol** (often known as “bad cholesterol”). Reducing LDL cholesterol levels is crucial to help prevent ASCVD and lower the risk of cardiovascular events.



What is this study about?

Treatments like statins and other existing medicines help people manage their LDL cholesterol levels. However, for some people, these treatments do not lower LDL cholesterol levels enough and they remain at higher risk.

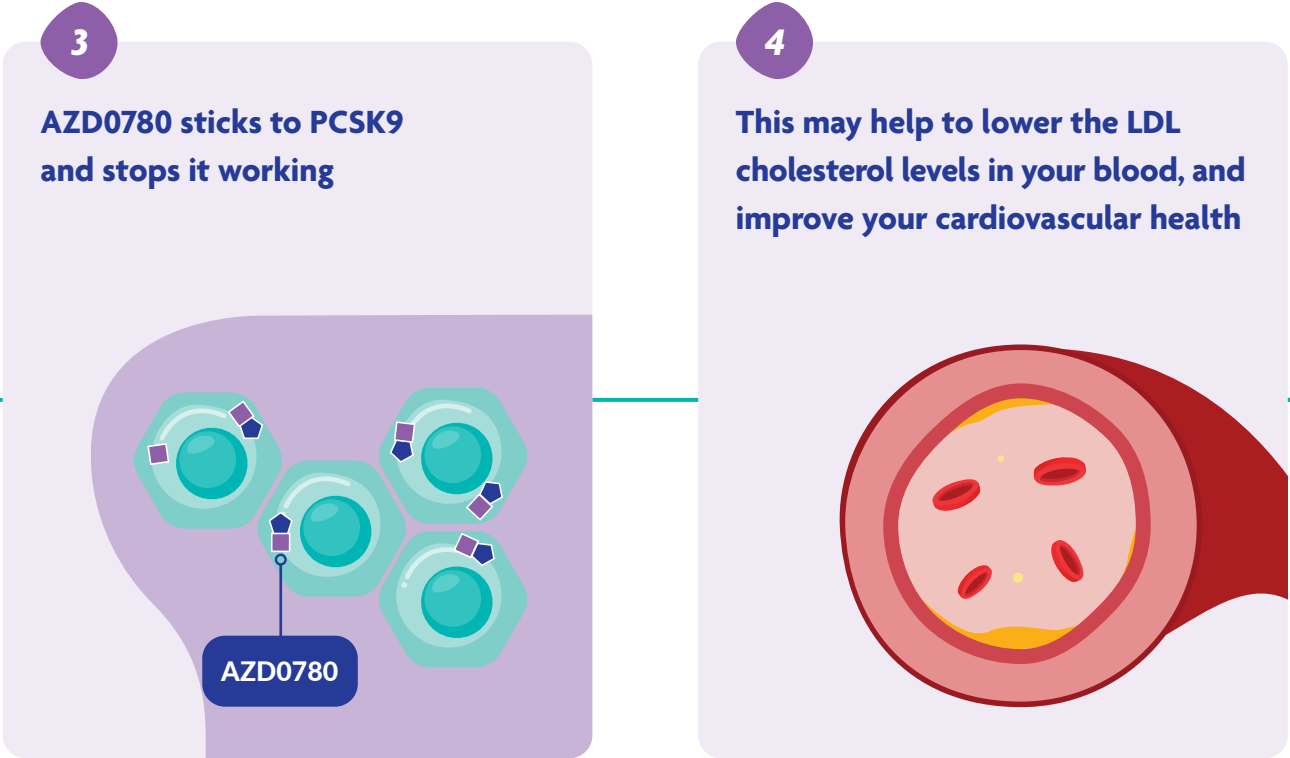
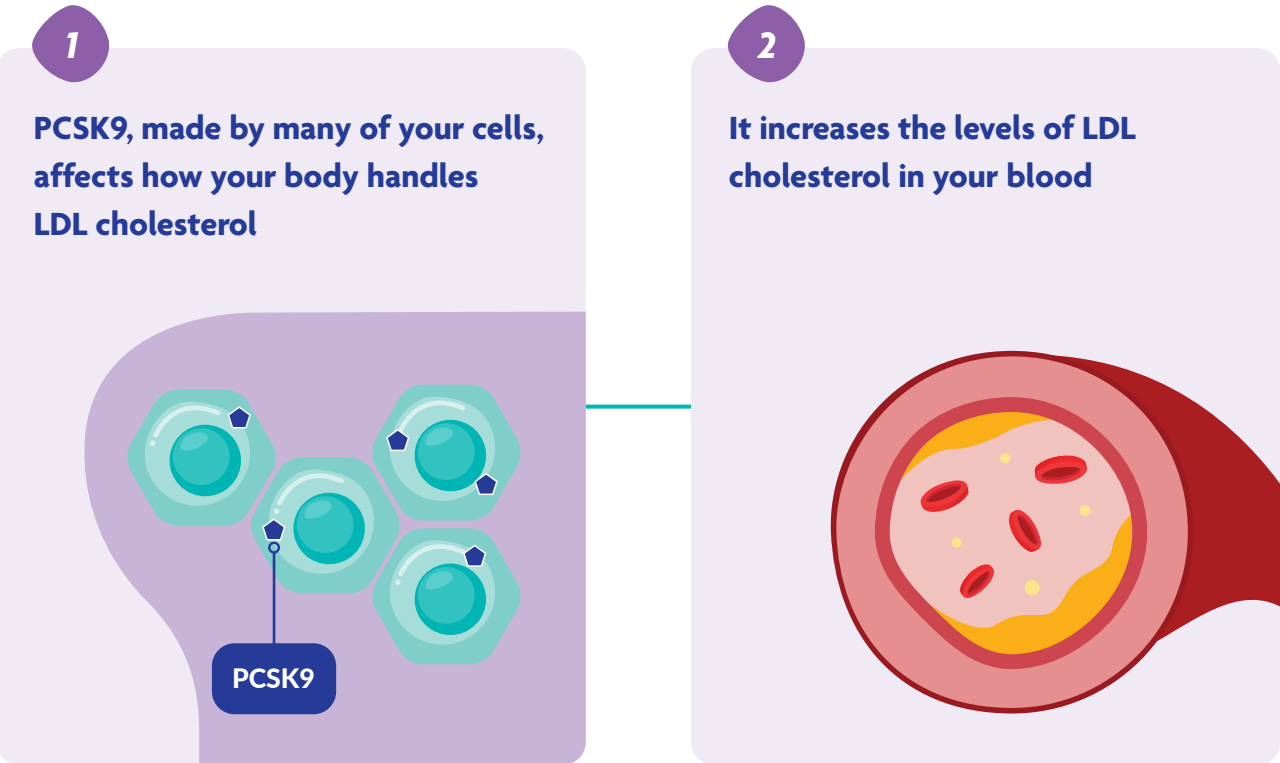
A group of treatments, called **PCSK9 inhibitors**, are known to help reduce LDL cholesterol levels. However, these are currently all given as **injections**, which we know may not be convenient for some people. New, easy and convenient treatment options are needed to support those living with ASCVD or at risk for ASCVD-related events.

This study is looking at an oral PCSK9 inhibitor called AZD0780. We want to find out whether it may help to reduce LDL cholesterol levels and the risk of cardiovascular-related events or medical procedures. By taking part in this study, you're helping us look for new ways to improve care and outcomes for people like you.

AZD0780 has been **tested already** in healthy volunteers and in some people with high LDL cholesterol. Results from this research have supported further testing, to find out more about how it works.

What is the study treatment?

AZD0780, like other PCSK9 inhibitors, is designed to block a protein, made by your body, called **PCSK9**.



Will I definitely receive AZD0780 if I take part?

To better understand how well AZD0780 works, the study will compare it with a **placebo**. The placebo looks like the study drug and is taken in the same way, but it doesn't contain any active medicine. If you do take part in this study, you will have a **1 in 2 (50%) chance of receiving AZD0780**.

How will I take the study treatment?

Both AZD0780 and the placebo are taken by mouth as a **tablet, once a day** with or without food.

What about my regular treatments?

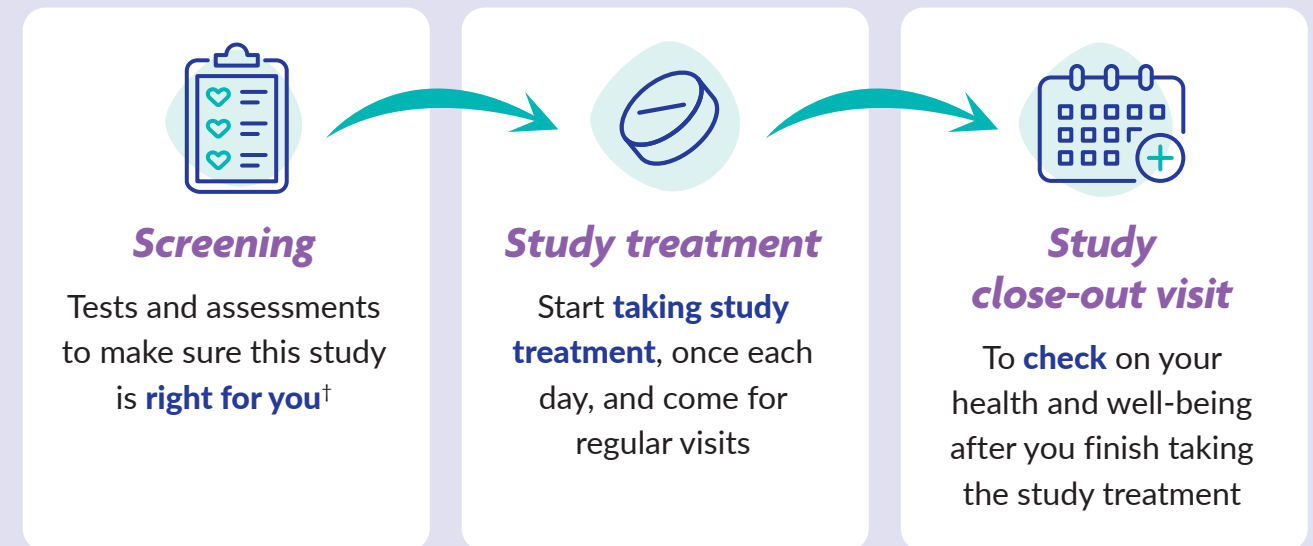
You'll be able to **keep taking your usual cholesterol-lowering treatments** throughout the study. The study doctor will let you know if there are any treatments you'll need to stop taking.



What can I expect if I take part?

If you do join the study, you will be asked to attend regular study visits for **up to 4.5 years***.

The study is split into a few different parts:



Because this study is looking at how AZD0780 may help protect cardiovascular health, it will continue until a certain number of people have a cardiovascular-related event or medical procedure. This means the length of time you receive the study treatment may **vary, depending on when you join (**from 2.5 years to 4.5 years**). The study doctor will be able to discuss this with you in detail.*

[†]If the study is not right for you, the study doctor will explain the reasons and discuss all other available treatment options with you.

What will happen during study visits?

Study visits are an important way for the study team to monitor your health and give you any support you need. During these visits, the study doctor will ask about how you're feeling, check for any changes in your health, and answer any questions you may have.

*At each visit, you may have tests as part of your routine care.
As part of the study, you may also have:*



Blood tests



Electrocardiograms (ECGs)



Urine tests



Physical exams



Pregnancy tests (if applicable)



Vital sign checks (including blood pressure and pulse)



Questionnaires about how you're feeling



Study visits will normally take up to a few hours. We understand these may be more frequent or longer than your routine check-ups, but they're carefully planned so the study team can closely monitor your health and give you any support you need.

You may have the option to reschedule visits, and you may also be paid back for any travel or parking costs.



Will I need to do anything at home?

Before visits, you will be asked not to eat or drink anything apart from water (**fast**) for at least 8 hours, and **avoid changes to your exercise routine** for at least 5 days. The study team will also provide guidance and support so you can follow a **heart-healthy diet**.

What should I consider while I make my decision?

We understand that taking part in a clinical study is a big commitment. It may mean:

- ✓ Access to a potential **new treatment**
- ✓ More frequent and detailed **health checks**
- ✓ **Support and guidance** to help manage your condition
- ✓ Helping to **develop new treatments** for you and other people in the future



But, there are lots of other things to consider too:

- As with all medicines, there is a chance the study treatment may cause some **side effects**
- If you do take part, you will have a **1 in 2 (50%)** chance of receiving a **placebo**
- We do not know yet what effect AZD0780 may have on an unborn child. This means you won't be able to join the study if you're **pregnant** or planning to become pregnant
- As part of this study, we'll need to use your **data and samples**, and in some cases, share or publish the findings. We will always store your information securely, will never share it with any insurance companies or for marketing purposes, and will never share or publish anything that could be used to identify you

It's important that you weigh everything up carefully. Remember, the choice to take part is always yours.