



**HPS-4
TIMI 65
ORION-4**

**Final Follow-Up
Participant
Information Leaflet**

**Information about the end of your
active participation in ORION-4**

Introduction to this leaflet

Thank you very much for your participation in the ORION-4 trial. We are very grateful that you have been so generous with your time and commitment to the study. Without volunteers like you, we would not be able to find the best way to treat people with cardiovascular disease (also called heart and circulatory disease).

As you know, ORION-4 is a research study aiming to find out if a new cholesterol-lowering injection called inclisiran safely lowers the risk of heart attacks, strokes and other health problems in people with cardiovascular disease.

You will be asked to complete your final follow-up assessment for the study in the next few months. We would ask that you attend this final follow-up in person, if possible, even if your previous follow-up assessments were by telephone. It helps the study to produce reliable results if a blood sample is taken from as many participants as possible at the final follow-up assessment.

This information leaflet aims to answer some of the questions you may have now that your active participation in the study is coming to an end.

If you would like to discuss this or any other part of the ORION-4 study, please contact the study coordinating centre using the contact details at the end of this leaflet.

When will the results of the study be available?

The results of ORION-4 will not be available until Spring 2027. This is because the study team needs time to complete all the final follow-up assessments, check all the information that has been collected, and analyse the data.

How can I find out the results of the study?

We will write to you with the results of the study when they become available. The results will also be available on the study website www.orion4trial.org.



How can I find out whether I was getting the active medication or the placebo?

It helps the study produce reliable results if neither you, your doctors, nor the study staff know which treatment you were allocated to receive until after the analysis of the study results has been completed. After we write to you with the results of the study in Spring 2027, you can find out whether you were receiving the active inclisiran injections or the placebo injections by contacting the ORION-4 coordinating centre (contact details at the end of this leaflet). We will remind you about how you can do this when we write to you next year with the results.

What happens to my cholesterol lowering treatment now?

You will not receive any further injections of ORION-4 study treatment. You should continue to take any medications prescribed by your usual doctors. If you were receiving the active inclisiran injections, this may continue to affect your blood cholesterol readings for at least one year after your last injection. The ORION-4 team will not be able to provide ongoing inclisiran injections. Incisiran is available within the NHS for some patients and you may wish to discuss this with your GP. If the results of ORION-4 show that inclisiran helps to protect against heart attacks and strokes, then we hope that it will become widely available.



What has my GP been told about the end of my participation in the study?

Once you have completed your final follow-up assessment, your GP will be told that your active participation in ORION-4 has come to an end and the date that you last received a study injection. We will write to your GP again with the study results once they are available in early 2027.

Is the ORION-4 study continuing to collect health data about me?

Once you have completed your final follow-up assessment, your active participation in the study will come to an end, but long-term follow-up of UK participants will continue.

The ORION-4 long-term follow-up aims to find out whether any beneficial effects of inclisiran on heart attacks, strokes and other cardiovascular conditions continue after stopping the treatment and whether inclisiran has any other long-term effects. The ORION-4 long-term follow-up may also be used to study other important health conditions and to develop better ways of doing this type of research. We can do this using data from the NHS without needing to contact you.

When you joined the study, you were asked whether you agreed for the ORION-4 team to receive information about you held by national registries or NHS bodies after the end of your active participation in the study (including sending your identifiable data securely to such bodies to make this possible). If you gave consent for this, then the ORION-4 team plans to continue to collect health information about you from national registries and NHS bodies, including NHS England (previously called NHS Digital), the SAIL databank at the University of Swansea, and Public Health Scotland. This could also include collecting health data recorded at your GP practice. The data would include information about cancers, admissions to hospital, prescribed medications, serious illnesses and any deaths that may occur.

If you no longer wish to let the ORION-4 team collect this information about you, please telephone, write to, or email the study team (see contact details at the end of this leaflet). Please make sure to include your ORION-4 participant ID in any communication.



What will happen to the data collected about me for ORION-4?

When you joined the ORION-4 trial you were given a Participant Information Leaflet which explained what happens to data collected about you for ORION-4. You can find a copy of the Participant Information Leaflet and more information about how data about you is processed for ORION-4 at www.orion4trial.org.

What should I do now?

If you have an appointment for an in-person follow-up visit in the next few months, you don't need to do anything other than attend your appointment. If you don't have an appointment booked, or have an appointment for a telephone follow-up assessment but would be willing to attend in-person, please contact the ORION-4 team using the contact details at the end of this leaflet.

Thank you very much for supporting ORION-4. You have made a really valuable contribution to this important study.

Contact information

Please contact the ORION-4 office if you would like to receive this document in another format.

If you have any questions you can contact the ORION-4 team:

By phone:

24-hour Freephone number:

0800 585323

By post:

ORION-4

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