

What are the benefits and risks of being in this study?

One benefit of taking part in this study is that your health will be monitored frequently. However, there is no guarantee that this study will improve your health. It may stay the same or it may get worse. Also, as with all drugs, the study drugs may cause side effects. We may be able to prevent or manage some of these and many go away quickly. Any study has risks, which may include things that could make you feel sick or uncomfortable or could cause harm. The study staff will review potential risks before study enrollment.

Can I decide not to be in the study?

Taking part in a clinical study is voluntary. If you are eligible to enroll, you may choose to join the study but leave at a later date for any reason at any time. Regardless of whether you choose to enroll or leave the study early, your future healthcare won't be affected.

How can I learn more about this study?

To learn more, please visit www.gskoceanclinicaltrial.com or scan the code below.



NOW ENROLLING

The OCEAN Study

for adults with eosinophilic granulomatosis with polyangiitis (EGPA)

A quick reference guide for potential participants in the OCEAN study

Thank you for your interest in the OCEAN study. This fact sheet provides more details about the study so you can decide if you want to find out more information. If you have questions or would like to know more, please visit www.gskoceanclinicaltrial.com or scan the code on the back cover.



What is this study?

The OCEAN clinical research study is looking for participants who are 18 years of age or older with eosinophilic granulomatosis with polyangiitis (EGPA) that has worsened or returned after previous treatment. Study doctors are testing an investigational drug given as injections, to find out if it works compared to an approved drug, and to determine the investigational drug's safety in people living with EGPA.

Half of the study participants will receive the investigational drug (depemokimab) and the other half will receive an approved drug (mepolizumab). Both study groups will also receive placebo injections plus standard EGPA therapy as prescribed by a doctor.

An investigational drug is one that is not approved for use by the general public. Placebo is a substance that looks like the study drug but has no active drug in it. Your study group assignment is blinded, meaning you and your study doctor will not know which study group you are in.

Who is this study enrolling?

Approximately 160 participants will take part in this study. You may qualify for this study if you:

- Are at least 18 years of age or older
- Have EGPA that has worsened or returned after previous treatment
- Are currently taking a corticosteroid or immunosuppressant (your doctor will let you know if you may be eligible based on your current therapy)

Why is this study important?

EGPA is a rare condition where certain types of cells in your body swell. EGPA can affect several body organs including the heart, lungs, skin, gastrointestinal tract, kidneys, and nervous system. People living with EGPA are in need of more effective therapies for this condition. The purpose of this study is to evaluate the safety and effectiveness of an investigational drug (depemokimab) administered every 26 weeks compared to mepolizumab administered every 4 weeks.

How are the study drugs being tested?

In this study, you will be assigned to a study drug group. You will receive either:

- An investigational drug (depemokimab) given as injections every 26 weeks (plus placebo injections every 4 weeks and your standard EGPA therapy as prescribed by your doctor)
- OR
- An approved drug (mepolizumab) given as injections every 4 weeks (plus placebo injections every 26 weeks and your standard EGPA therapy as prescribed by your doctor)

You will not be told which group you are in.

How long will I be in this study?

After the 4-week screening period, you will receive study injections for up to 52 weeks, and then receive 1 follow-up phone call about 4 weeks after your last study injections so study staff can ask you safety questions.

How will my health be monitored in this study?

During the study, you will visit the study site regularly for health checks and several types of tests and assessments. These may include:

- Physical exams
- Vital signs measurements (body temperature, blood pressure, and heart rate)
- Electrocardiograms (to measure the electrical activity of the heart)
- Blood and urine tests
- Questionnaires from study staff and in the eDiary (at Visit 1, you will be trained on how to use the eDiary at home to complete some questionnaires)

Not all of these activities will occur at every visit. There are a total of 17 visits as part of this study. Study visits will usually take place at the study site and depending on local regulations, it may be possible for some health checks and assessments to take place at your home either in-person or by video consultation.