

What is a clinical research study?

Clinical research studies help scientists and doctors explore whether a drug or device is safe and effective at treating a condition in humans. Before an investigational drug can be used for therapy, it must go through several phases of clinical research:

- Phase 1: First study of the drug in humans (often healthy volunteers).
- Phase 2: Study to gather information about the safety and effectiveness of the drug.
- **Phase 3: Study confirming how effective the drug is for improving a specific condition.**
- Phase 4: Continued research after the drug is approved for public use.

The Oasis study is a Phase 3 study.

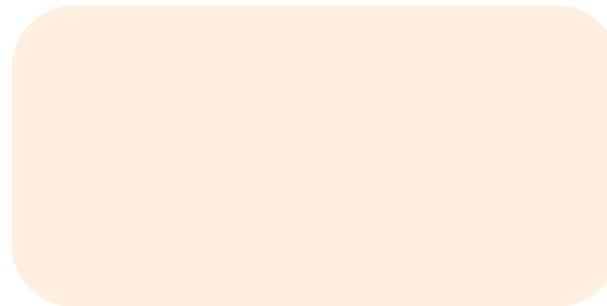
Specific standards apply to clinical research studies to protect participants.

What else do you need to consider?

- Taking part in a clinical research study is entirely voluntary. Participants can choose to leave the study at any time.
- Study participants will be carefully looked after by a team of doctors and nurses.
- All study drugs and study-related assessments will be provided at no cost. Participants will be reimbursed for certain costs associated with study visits, like mileage and parking.
- Participants may not receive any benefit from the Oasis study and may experience side effects. However, the information gathered from the study may be used to help other people with HAE in the future.

Want to know more?

Call **844-501-0233** or contact:



Do you or a loved one experience frequent HAE attacks?

Learn more about Oasis, a clinical research study for people with hereditary angioedema (HAE).

Ask your doctor if the Oasis study may be right for you!

Thank you for your interest in the Oasis study.

The Oasis study is a clinical research study sponsored by Ionis Pharmaceuticals, a company developing a potential new therapy for HAE. This study will help researchers learn whether an investigational study drug is safe and effective at reducing or preventing HAE attacks.

What is HAE?

HAE is a rare and potentially life-threatening genetic disease that causes painful swelling attacks in various parts of the body, mainly in the hands, feet, face, throat, and stomach area. Swelling in the airway can restrict breathing and be fatal. A HAE attack may be triggered by emotional trauma or stress; however, an attack often occurs without a known trigger. Attacks can occur without warning and last up to several days if untreated.

What is the study drug?

The study drug is called donidalorsen (don-id-a-lor-sen). It is uniquely designed to lower the amount of a protein called prekallikrein (PKK) in the body. When PKK is released into the bloodstream, it can lead to HAE attacks. By lowering PKK, donidalorsen may help reduce or prevent HAE attacks.

It is **investigational**, which means it can only be used for research studies. It has not been approved by regulatory authorities like the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) as a therapy for HAE.

Who can join the study?

You may qualify for the Oasis study if you meet the following requirements:

- You are 12 years of age or older.
- You have been diagnosed with HAE.
- You have access to at least 1 acute medication to treat HAE attacks.

Other requirements will apply.

What can you expect if you join the study?

The Oasis study lasts up to 46 weeks (a little less than 1 year). If you decide to join, you can expect the following:



Complete the Screening Period (up to 8 weeks) to confirm you qualify for the study.



Be randomly assigned to receive injections of the study drug or placebo (no active ingredients) once every 4 or 8 weeks.



Attend up to 10 study clinic visits (about 1 visit every 4 weeks) to receive injections and health assessments, like a physical exam, blood test, and heart test (ECG). Some visits may take place at home.



After you complete 7 study visits, you may have the option to join an open-label extension study in which all participants receive the study drug (no placebo).

