OASIS

Informed Assent Process Guide

V1 | 11NOV2021 | ISIS721744-CS5

Talking points for investigator/study coordinator

How to use this guide

- Introduce yourself and explain your role in the study process.
- Explain the purpose of the Assent Form.
- Let the participant know that they can ask questions at any time as you go through this guide.

How to use this guide

This guide is designed to help you understand the informed assent process for the Oasis study.

“Informed assent” means that you have learned about the study requirements and are agreeing to participate.

Talking points for investigator/study coordinator

What is the purpose of the Oasis study?

- Review overall study objectives.
- Answer any questions about clinical research studies.

What is the purpose of the Oasis study?

You are being asked to join the Oasis study because you have a condition called hereditary angioedema, or HAE.

We want to see if giving the study drug to people with HAE has an effect (good or bad) and if it is safe.

What is the study drug?

- Explain what the study drug is designed to do.
- Explain what “investigational” means.
- Answer any questions about the injection procedure.
- Explain that while we are still learning about the safety of the study drug, other people have taken it before as part of an earlier clinical trial.

What is the study drug?

The study drug is an investigational new therapy for HAE called donidalorsen (don-id-alorsen). The goal of donidalorsen is to lower the amount of a protein that can lead to HAE attacks. By lowering this protein, donidalorsen may help reduce or prevent HAE attacks.

Donidalorsen is an injection that is administered in the upper arm, abdomen, or thigh every 4 or 8 weeks.

Talking points for investigator/study coordinator

Will I receive the study drug?

- Explain how the randomization process works.
- Explain that neither the study team nor the participant will know whether they are receiving study drug or placebo.

Will I receive the study drug?

You may or may not receive the study drug.

You will be randomly assigned to receive the study drug or placebo. Placebo looks like the study drug, but it does not have any active ingredients.

Both the study drug and placebo are given as an injection.

Talking points for investigator/study coordinator

What will happen during the study?

- Explain the different parts of the study:
  - **Screening Period**
    - Up to 8 weeks (2 months).
    - 1 study visit.
  - **Treatment Period**
    - 25 weeks (almost 6 months).
    - 7 study visits.
    - Injection at 3 or 6 study visits (every 4 or 8 weeks).
  - **Follow-up Period**
    - 13 weeks (a little more than 3 months).
    - 3 study visits.
- Discuss home healthcare options.

What will happen during the study?

This study lasts almost 1 year. During this time, you will have 11 study visits, including this visit. Most study visits will last about 2 hours. Three study visits (including this one) may last about 4 hours.

At study visits, you will receive some health tests and assessments. You will also receive 1 injection of the study drug or placebo at either 3 or 6 of the study visits, depending on what group you are in.

Talking points for investigator/study coordinator

Will the study tests hurt?

- Explain what will happen during study visits.
- Describe common tests and assessments.
- Answer any questions about tests and assessments.

Will the study tests hurt?

You will receive different tests and assessments during the study, like a physical exam, blood tests, and a heart test. You will also answer questions about your HAE. Your parent/guardian can stay with you during tests and assessments if you'd like.

Some study tests might hurt or cause you to feel some discomfort. Let the study team know if you are worried or uncomfortable, and they will do everything they can to help.

Talking points for investigator/study coordinator

What are the risks and benefits of participating?

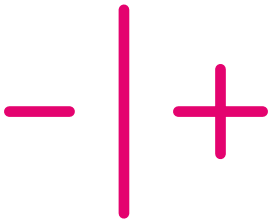
- Explain the risks and benefits of participation.
  - Mention that participation can be difficult for teenagers because study commitments may interfere with social or school activities.
- Answer any questions about the risks and benefits of participation.
- Ensure parents/guardians are aware of the list of signs and symptoms that should be reported to the study team.

What are the risks and benefits of participating?

You may or may not feel better while participating in this study. What doctors and researchers learn from this study might help other people with HAE in the future.

If you feel unwell at any point during the study, please tell your parents/guardian.

Participating in research can sometimes be difficult. If you are worried about the study and how it affects your life, talk to someone like a teacher, parent/guardian, or doctor.



Talking points for investigator/study coordinator

Are there costs to participate?

- Explain that there is no charge to participate.
- Explain which costs will be reimbursed.
- Explain how reimbursement works.
- Indicate who to contact if participants have questions about reimbursement.

Are there costs to participate?

You and your parents/guardian will not need to pay for you to take part in this study. You or your parents/guardian may receive money to cover your time and effort for participating.

Talking points for investigator/study coordinator

How will privacy be protected during the study?

- Explain the types of personal information that will be protected:
  - Name.
  - Age.
  - Health information.
  - Details about the participant's HAE.
- Answer any questions about privacy.

How will privacy be protected during the study?

Any information that the study doctor collects about you will be protected and kept private.

If you are worried about anyone knowing anything about you participating in this study, talk to your study doctor or your parents/guardian.

Talking points for investigator/study coordinator

Do I have to join this study?

- Explain that participating in a clinical research study is completely voluntary, and the participant can choose to stop at any time for any reason.
- Explain that if the participant decides to join the study, they will need to sign the Assent Form.

Do I have to join this study?

Being part of the Oasis study is your choice. No one will be mad at you if you do not want to join.

If you say yes to being in the study now, you are allowed to change your mind later for any reason.

Talking points for investigator/study coordinator

Thank you

- Thank the participant for their consideration.
- Confirm that the participant does not have any additional questions.
- Remind the participant to read the Assent Form. Tell them to take some time to think about the study and discuss with a parent/guardian before making a decision.

Thank you

Thank you for considering the Oasis study!

We invite you to ask the study team any other questions you might have about the study.

Take some time to read the Assent Form, think about the study, and talk with your parent/guardian before making your decision. If you decide you want to join the study, you will need to sign and date the Assent Form before you can begin.

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