

# The Study in Pediatrics with HypEREosinophilic syndrome (SPHERE)

## Patient Advocacy Group Study Fact Sheet

Thank you for your interest in learning about the SPHERE study. This fact sheet provides more details about the study that you can share with families of children with hypereosinophilic syndrome (HES). If families have any questions or would like to know more, please direct them to call the local study site at the number below.

### What is the SPHERE study?

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In this clinical research study, doctors are testing an investigational drug (mepolizumab) to see how it works long term on HES symptoms in pediatric patients.

### Who is this study enrolling?

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The SPHERE study is looking for approximately 25 participants with HES between the ages of 6 and 17 years old.

### Why is this study important?

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This study can help doctors research the possibility of long-term relief of HES symptoms in pediatric patients. Clinical studies (also called “clinical trials”) help doctors learn more about investigational drugs and answer questions about how they work, if they work better than other treatments, and if they have side effects. Current treatments for diseases are only available because of research study volunteers.

### What should participants know about the SPHERE study?

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- To be eligible for this study, participants must\*:
  - Be between 6 and 17 years old
  - Have a diagnosis of HES for at least 6 months
- The health and safety of participants will be monitored throughout the study
- Participant data and information will be kept confidential
- Study participants will receive all study-related procedures and the study drug at no cost
- The study doctor will provide participants with a letter to their school to explain absences during any study visits

*\*This is not a full list of requirements. The study doctor will review the full requirements for this study with potential participants.*

## How long will this study last?

Participants will be followed in the SPHERE study for approximately 1 year and 3 months. Eligible participants may enter an expanded access program (EAP), where available, immediately after completion of the 52-week treatment period.

When participants stop or complete the study, the study doctor will continue to assess their health condition. Participants will have a follow-up visit approximately 12 weeks after the last dose of the study drug (only if they did not enter the EAP).

## How will participants' health be monitored in this study?

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

- Physical examinations
- Vital signs measurements (body temperature, breathing rate, blood pressure, and heart rate)
- Electrocardiograms (to measure the electrical activity of the heart)
- Blood and urine tests
- Assessments and questionnaires

Not all of these activities will occur at every visit.

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

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

## Is participating in this study voluntary?

Taking part in a clinical study is voluntary and participation may be withdrawn at any time. Regardless of whether a participant chooses to enroll or leave the study early, their future healthcare will not be affected in any way (i.e., participants will not be penalized for study enrollment or discontinuation).

### How can patients learn more about this study?

For more information about your nearest study site, please visit [www.sphereclinicaltrial.com](http://www.sphereclinicaltrial.com) and click on your location on the world map where participants or their parents/legal guardians can contact us. You can also call the local study site at the number below.

**Study site phone number:** \_\_\_\_\_

**Office hours:** \_\_\_\_\_

This content has been reviewed by APFED and CURED for language clarity and readability. For more information about hypereosinophilic syndrome and to find support, please visit [apfed.org](http://apfed.org).