

Who can take part in the BRIDGE Study?

Patients with Fabry disease may be able to take part if they:

- are 18–60 years of age
- are experiencing symptoms of Fabry disease, such as pain or clusters of dark spots on the skin known as angiokeratomas
- have been receiving agalsidase alfa infusions for at least 2 years

For patients interested in taking part, the study team will ask some medical history questions and carry out health assessments at the study center to see if the study is a good fit.

What else do you need to consider?

Taking part in the study is entirely voluntary. Patients can leave the study at any time. Anyone who takes part in the study will be carefully looked after by a team of experienced doctors and nurses. The study medication and study-related healthcare procedures will be provided at no cost. In addition, reasonable travel expenses will be reimbursed.

Patients who take part in the BRIDGE Study may or may not benefit from their participation. Patients may have side effects from the investigational medication, or their condition could get worse. However, the information gathered from this study may be used to help other patients with Fabry disease in the future.

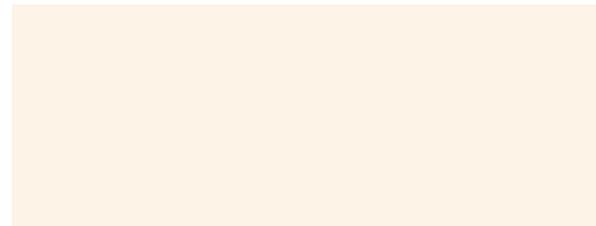


Coming together to help improve outcomes in Fabry disease

Want to know more?

The BRIDGE Study Team will be happy to give you more information or to answer any questions. You can contact them using the details provided below. Patients may find it helpful to speak with their families or personal doctors about taking part in the study before making a decision.

Thank you for your interest in the BRIDGE Study.



Introducing the BRIDGE Study

For patients with Fabry disease

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The BRIDGE Study is a clinical research study that will evaluate the safety and efficacy of an investigational medication (a potential new medication) in patients treated before with an approved medication (agalsidase alfa, also known as Replagal) in patients with Fabry disease. The investigational medication is a type of medication called “enzyme replacement therapy,” or ERT. The investigational medication has been designed to help the body break down the particular fat (lipid molecule) that builds up in the body’s cells because of Fabry disease.

The investigational medication in the BRIDGE Study is a new ERT. It is designed to last longer in the body, which might help protect the body’s organs from the effects of Fabry disease and reduce symptoms.

What is a clinical research study?

A clinical research study is an investigation that helps us learn whether a potential new medication is effective and safe. All new medications must be tested in a series of clinical research studies before they can be approved and prescribed for use.

- Phase 1 studies look at the investigational medication for the first time in a small group of people.
- Phase 2 studies give the investigational medication to a larger group of patients to find out more about its safety and efficacy.
- Phase 3 studies, like the BRIDGE Study, give the investigational medication to a larger number of patients to evaluate its efficacy and learn more about its side effects or how it is best used.

Without clinical research studies, no new medicines would be developed and few medical advances would be made. These studies are overseen by local and national regulatory bodies.

What is the BRIDGE Study?

The BRIDGE Study one of a group of a Phase 3 clinical research studies and involves about 22 patients with Fabry disease who have been receiving agalsidase alfa infusions for at least 2 years.

All patients will continue on their current dose of agalsidase alfa for the first 3 months of the study. These 3 months are called the screening period. If patients qualify for the study after this screening period they will then receive the investigational medication. The investigational medication is given as an infusion (via a drip into a vein in the arm) every 2 weeks for 12 months. At the end of the study, patients may have the option of continuing with the investigational medication.

What will the BRIDGE Study involve?

The study has two periods and up to 56 visits.

Screening period

Approximately 3 months, 3 visits

- The study doctor will ask questions and do some health checks to see if the study is a good fit.
- You will continue on your current dose of agalsidase alfa during this time.



Treatment period

Up to 1 year, 27 visits

- Infusions (1 mg/kg) of the investigational medication every 2 weeks.
- Each infusion will take up to 3 hours, but this may be shortened over time.
- Questions, health checks, and other assessments will be done to monitor patient health and learn about the investigational medication.



After the treatment period

- Final health checks will be done at 1 month and 3 months after the last infusion visit.
- Patients may be able to join a long-term study in which they will all receive the investigational medication.