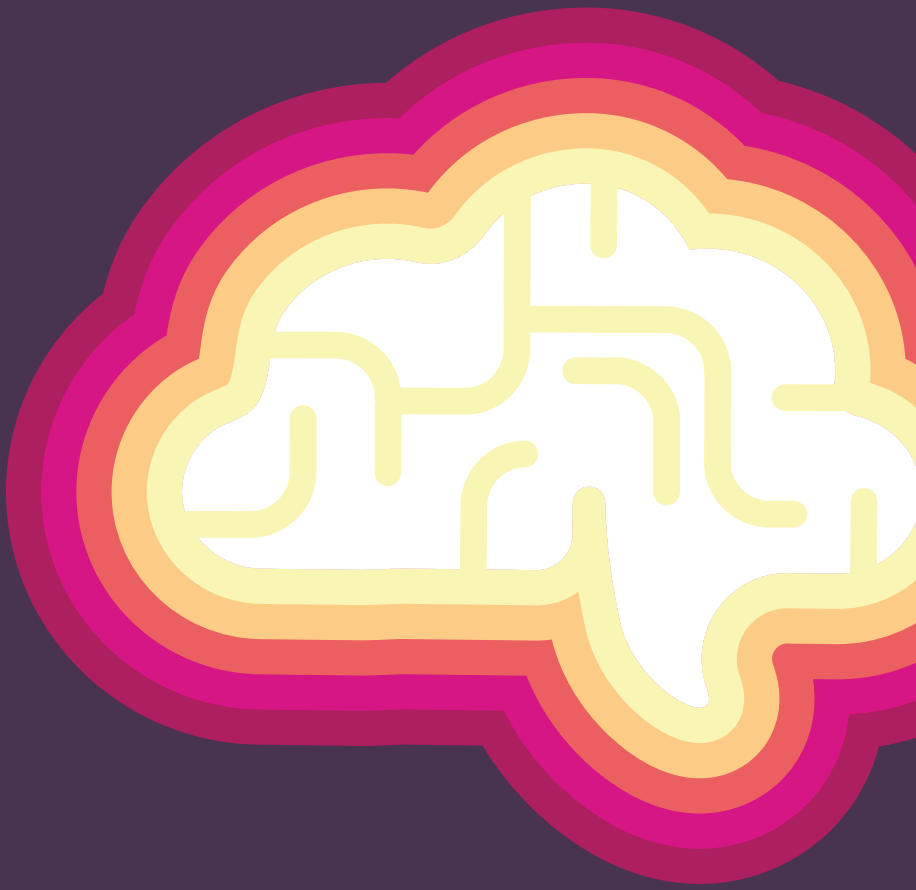
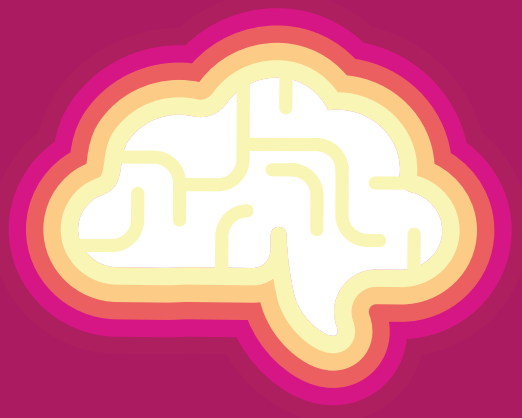


Information About the CHARM Study for Large Hemispheric Infarction (LHI)

CHARM

M-GLI-US-00009



Every minute counts when you or a loved one have a stroke.

We're conducting a new clinical research study that may be of interest to you. The CHARM study will assess the safety and potential effectiveness of an investigational drug in people who:

- Have had a large hemispheric stroke
- Can start study treatment within 10 hours from the time that stroke symptoms began or the time they were last seen to be well
- Are 18 to 85 years old
- Meet other study eligibility criteria, which the study team will discuss with you

This brochure will provide you with information about clinical research in general, explain why we're conducting the CHARM study, and describe what participation in this study involves.

What is a clinical research study?

A clinical research study is a scientific investigation designed to answer important questions about an investigational drug, such as:

- How well does it work?
- Which dose works best?
- What are the side effects?

People take part in clinical studies for a number of reasons. For example:

- There may be few or limited treatment options available
- They may want to help others like them or add to our knowledge of their disease or condition

Even before a study starts, safety is our highest priority. Every study must be reviewed and monitored by either an Institutional Review Board (IRB) and/or an independent Ethics Committee (EC). These groups (made up of both scientists and non-scientists) review the study's plan to make sure:

- The rights of patients and their study partners are protected
- There are no unnecessary risks involved
- The study answers important unanswered medical questions

BIIB093 is an investigational drug that is not approved by any health authority and its safety and effectiveness have not been established.

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What important medical question does this study ask?

As you may know, every minute counts when it comes to treating a stroke. This is especially true for LHI because the only approved treatment options must be administered within four-and-a-half hours of symptom onset. However, these treatments may not always work for everyone. In addition, there is no approved treatment to reduce the swelling in the brain caused by increasing fluid build-up (a condition known as cerebral edema), which is a major cause of LHI-related complications.

The CHARM study will assess an investigational drug which may potentially help block protein receptors involved in the development of cerebral edema (accumulation of fluid in the brain) after a stroke. By blocking the activity of these protein receptors, this investigational drug is being evaluated to see if it may prevent or reduce cerebral edema, which might reduce brain swelling and may result in improved outcomes in people who have had a LHI.

Because of this, we're conducting the CHARM study to learn more about this investigational drug—its safety profile and its potential impact on functional outcomes. The study will also aim to evaluate the investigational drug's long-term effects after a LHI.

What will happen during the study?

SCREENING

Before beginning the study, participants will undergo screening assessments to make sure they understand and meet all the requirements for study participation.

DOSING

Participants will receive the investigational drug or placebo and visit with the study team regularly for study assessments. The investigational drug or placebo will be given as an intravenous (IV) infusion (through a needle into the vein) over a 72-hour period.

FOLLOW-UP

Participants will have a visit or phone call with the study team four more times to continue monitoring each participant's condition over the course of one year.

A placebo is a substance that looks like the investigational drug, but contains no active ingredients. Placebos help us to make sure that any changes seen during the study are due to the investigational drug and not another reason. Participants in the CHARM study will be assigned a group at random (by chance) to receive either the investigational drug or the placebo. Neither the participants nor the study team will be told which group each participant is assigned to until after the study has finished.

How will participants' health be monitored during the study?

As safety is our highest priority, participants will be closely monitored by the study team throughout the study. For this study, assessments will be conducted every 12 hours over the first 72 hours of study participation. The study team will also conduct study assessments again a few days later (after seven days in the study or upon discharge from the hospital). Participants will also have four follow-up visits or phone calls with the study team for additional monitoring over the course of one year.

The study assessments will vary from visit to visit, but may include:


Physical examinations


CT or MRI scans


Medical history and medication reviews


Blood tests


Electrocardiograms (ECGs)


Health questionnaires

Some of these assessments may be a little uncomfortable and/or carry certain risks, but the study team will explain each assessment in detail if you or your loved one take part in the study.

Are there any potential risks?

It's important to remember that, as with any treatment, you can never be sure of the outcome of participating in a clinical study. A study participant's health may improve, it may stay the same or it may get worse. This could happen even for participants who are assigned to receive the placebo.

It's also possible that participants who are assigned to receive the investigational drug may experience side effects related to it. Some of these side effects are known to us already. For example, people who received the investigational drug in previous studies experienced:

- Low blood sugar (possible symptoms may include weakness, trembling, feeling faint, a fast or irregular heartbeat, and confusion or disorientation)
- Increased risk of cardiovascular (heart and blood vessel) issues
- Decrease in red blood cells
- Liver function abnormalities

However, there may be other side effects we don't know about yet. So, it's important you tell the study team if you or your loved one experience anything unusual during your time in the study.

Learn more!

If you or your loved one decide to take part in this study, all study-related drugs and assessments will be provided at no cost. You would also be reimbursed for your travel expenses. Participation is voluntary, and participants can leave the study at any point without penalty. To leave the study, we would just ask you to contact the study team, and they may ask you or your loved one to visit a study clinic for one final health check.

To learn more about the CHARM study, visit www.charmstrokestudy.com or contact:

Biogen

CHARM