ENERGY STUDY

As a participant in the ENERGY study, you will be randomly assigned to receive either an infusion of the investigational medication or placebo. The purpose of this document is to help you better understand what a placebo is and how it plays a role in this study. If you have any questions about the investigational medication, the placebo, or the study, please ask the study doctor or a member of the study staff.

What is a placebo?

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A placebo is an inactive treatment that is designed to look exactly like the investigational medication being studied. In a placebo infusion, the liquid used for the placebo typically consists of sugar or salt water. Both are safe for infusion.

Why are placebos used in research studies?

Placebos are used in research studies to help researchers better understand whether a new investigational medication is safer and more effective than no treatment at all. Typically, one group of participants receives placebo, and the other group(s) receives the investigational medication. This enables researchers to compare the effects observed in each of the groups and learn if the investigational medication affects a participant's medical condition and health differently than placebo.

What is the Placebo Effect?

Although placebo should have no effect on a participant, some participants get better or worse in a research study even when they do not receive any active medication. This is known as the "Placebo Effect." Some participants improve because of psychological reasons or because they are receiving a lot of care and attention. To determine whether a new investigational medication is safe and effective, researchers need to rule out the impact of the Placebo Effect.

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How could placebo affect the results of this study?

Because placebo is being used, it is possible that some patients may experience the Placebo Effect. As a result, it's important that you do your best to answer questions about your health honestly and completely so that the study team is fully aware when evaluating your condition.

Will I receive a placebo while in this study?

The study team and participants are "blinded" as to which treatment group the participants are assigned to, which means no one learns the group assignments until the study is over. This helps reduce possible biased responses that could affect the results of the research study.

What happens if I receive placebo and my condition worsens?

All participants will be closely monitored during the study and receive the same care. If there is a change in your condition (i.e. your condition worsens) while you are participating, the study team will inform you immediately and will discuss your options. A recommendation could be made that you discontinue your participation, or they may recommend active medical treatment. This will all be determined on an individual basis.

Will I be able to participate in the Open Label Extension (OLE)?

At the end of the double-blind phase of the study, participants will be evaluated to determine whether they qualify for enrollment in the OLE. Whether you received the investigational medication or placebo, all participants in the OLE study will receive the investigational medication. The objective is to gather information about the safety and long-term tolerability of the investigational medication. This phase of the study usually runs longer than the blinded phase of the study, and you may opt out at any time. The dosage of the investigational medication will be determined by the study team based on the criteria established in the study protocol.