DETERMINED TO PROTECT WHAT MATTERS MOST

azalea

The image depicted contains models and is being used for illustrative purposes only.

As a participant in the Azalea study, you will be randomly assigned to receive either an infusion of the investigational medication or placebo. The purpose of this study is to evaluate the safety and efficacy of an investigational medication in pregnancies at risk for HDFN. 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 team.

What is a placebo?

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 alternative treatments available to alloimmunized patients. Typically, one group of participants receives a 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 the placebo.

What is the Placebo Effect?

Although the placebo should not affect a participant, some participants' health status' change 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.

How could the placebo affect the results of this study?

Because a 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, which means no one learns the group assignments until the study is complete. This helps reduce possible biased responses that could affect the results of the research study. All participants will be closely monitored during the study and receive the same level of care.

What happens if I receive a placebo and my condition worsens?

You and your baby will be closely monitored during the study and receive the same level of care no matter which group you are assigned to. If there is a change in your or your baby's health while you are participating, the study doctor will inform you immediately and will discuss your options, as your physical and mental health are of paramount importance. Your doctor will treat you as needed and work with you to determine the next steps in your care plan. This will all be determined on an individual basis.

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