DETERMINED TO PROTECT WHAT MATTERS MOST

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Are you pregnant with a baby at risk for hemolytic disease of the fetus and newborn (HDFN)?
A clinical research study is now enrolling eligible participants.

What is the purpose of this study?

The purpose of this study is to evaluate the safety and efficacy of an investigational medication in pregnancies at risk for HDFN.

Am I able to participate?

The Azalea clinical trial is enrolling participants who:

- Have tested positive for red cell antibodies
- Have been diagnosed with HDFN in a prior pregnancy
- Are 18 to 45 years old

What's involved with participating in the Azalea study?

Participation in this clinical trial includes weekly intravenous (IV) infusions while visiting the trial site approximately 20 - 23 times during your pregnancy. After your child's birth, you will have three additional trial site visits over the course of six months, and your child will have six trial site visits over the course of two years.

As a participant in the Azalea study, you will be randomly assigned to receive an infusion of the investigational medication; this can be the active investigational medication or placebo (the randomization ratio is 2:1, respectively). Placebo does not contain any active medication.

Does participating in this study cost anything?

All participants in the clinical trial will be reimbursed for study required travel and receive study required medical care at no cost. The investigational medication will be provided at no cost to you. You will not be paid for other medical care or medications which are not part of the study. The investigational medication has not been approved for use by the FDA.

What can I expect on my first visit to the study clinic?

If you choose to join the study and sign the informed consent form, you will be asked to attend a screening visit with the study doctor. At this visit, you will undergo tests and procedures to determine your participation in the study.

The safety and efficacy of the investigational medication has not been established by any regulatory agencies.

You can quit the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

What if 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. You can withdraw from the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

Where do I find more information?

To learn more about this clinical research study, please visit AzaleaTrial.com or contact the study site at:

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