A Study on Hemolytic Disease of the Fetus and Newborn (HDFN) Through Global Registry

NCT07194070

Status	RECRUITING
Sponsor	Janssen Research & Development, LLC
Enrollment	175 participants

Key Eligibility Criteria

Inclusion (5)

- Pregnant with an estimated gestational age (GA) (based on ultrasound dating) up to week 24
- History of a previous alloimmunized pregnancy that included at least one of the following: Fetal anemia diagnosed by middle cerebral artery (MCA) doppler ultrasound; Received greater than or equal to (\>=) 1 intrauterine transfusion (IUT) as a result of hemolytic disease of the fetus and newborn (HDFN); Fetal hydrops; Stillbirth or fetal demise with fetal or placental pathology indicative of HDFN; Neonatal exchange transfusion due to HDFN; Neonatal simple transfusion due to HDFN; Neonatal hyperbilirubinemia due to HDFN; Positive direct antiglobulin test (DAT) in neonate
- Documented presence of maternal alloantibody based on local laboratory results during current pregnancy
- Evidence of an antigen-positive fetus corresponding to the current maternal alloantibody: Fetal antigen status confirmed by cell-free fetal DNA (cffDNA); OR Fetal antigen status confirmed by amniocentesis; OR Paternal genotype confirmed
- Pregnant participant or a legally acceptable representative has provided informed consent (per local regulations or ethics committee requirements) for the collection and use of their medical data and the medical data for their corresponding fetus-es/neonates/infants/children

Exclusion (2)

- Participant actively participating in an interventional trial of an investigational agent
- At risk for HDFN due to ABO being the sole alloimmunization antigen in the current pregnancy (that is, ABO plus another antigen is permissible)

Locations (10 total)

Riley Children s Hospital, Indianapolis, Indiana, United States
University of Cincinnati, Cincinnati, Ohio, United States
Oregon Health And Science University, Portland, Oregon, United States
... and 7 more locations