

A Study of Nipocalimab in Pregnancies at Risk for Severe Hemolytic Disease of the Fetus and Newborn (HDFN)

NCT05912517

Status	RECRUITING
Phase	Phase 3
Sponsor	Janssen Research & Development, LLC
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (8)

- Pregnant and an estimated gestational age (GA) (based on ultrasound dating) from Week 13^{0/7} to Week 18^{6/7} at randomization
- History of severe Hemolytic Disease of the Fetus and Newborn (HDFN) in a prior pregnancy defined as documented:
- fetal anemia as result of HDFN or fetal hydrops as result of HDFN or received greater than or equal to (\geq)1 IUT as a result of HDFN or
- fetal loss or neonatal death as a result of HDFN, with maternal alloantibody titers for Rhesus antigen D protein (RhD), Kell, Kell Rhesus antigen C protein (RhC), Rhesus antigen E protein (RhE), or RhC antigen above the critical levels (anti-Kell \geq 4; other \geq 16) and evidence of an antigen-positive fetus
- During the current pregnancy, presence of maternal alloantibody to RhD, RhC, RhE, or RhC antigen with titers above the critical level (anti-Kell \geq 4; other \geq 16) based on the designated central lab results at screening

... and 3 more (see full listing online)

Exclusion (14)

- Currently pregnant with a multiple gestation (twins or more)
- Evidence of fetal anemia prior to randomization in the current pregnancy
- History of severe preeclampsia prior to GA Week 34 or severe fetal growth restriction (estimated fetal weight $<$ 3rd percentile, based on local fetal growth normative standards) in a previous pregnancy
- Current uncontrolled hypertension
- History of myocardial infarction, unstable ischemic heart disease, or stroke

... and 9 more (see full listing online)

Locations (59 total)

University of California at San Diego, La Jolla, California, United States
Kaiser Permanente Los Angeles Medical Center, Los Angeles, California, United States
UC Davis School of Medicine, Sacramento, California, United States

... and 56 more locations

<https://clinicaltrials.gov/study/NCT05912517>

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