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A study of nipocalimab in pregnancies for severe hemolytic disease of the fetus and newborn (HDFN)

Submission date
04/10/2023

Recruitment status
Recruiting

Registration date
23/11/2023

Overall study status
Ongoing

Last Edited
02/07/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Hemolytic disease of the newborn and fetus (HDFN) is a rare and potentially life-threatening blood disorder in newborn babies and fetuses that occurs when the blood types of the pregnant individual and fetus/baby are incompatible, thus resulting in fast breakdown of red blood cells (RBCs) of the fetus/baby. This may lead to anemia (low hemoglobin levels), jaundice (yellow discoloration of the skin because of the high levels of the chemical, bilirubin in blood) and other related complications.

Currently, severe HDFN is most commonly treated by injecting donor red blood cells into the fetus, a procedure called intrauterine transfusion. Nipocalimab, the study drug in this trial, is a protein that targets and binds to a specific molecule called FcRn (neonatal fragment crystallizable receptor). These receptors are found throughout the body and also in the placenta. In pregnant individuals at risk for severe HDFN, nipocalimab aims to decrease the level of IgG (immunoglobulin G) antibodies* targeting fetal RBCs by binding to the FcRn receptor thereby decreasing IgG levels in the pregnant individual pregnant individuals IgG antibodies to the fetus across the placenta. Nipocalimab may be a less invasive option for managing severe HDFN.
*one type of protein that protects the body from infections caused by bacteria, viruses, and other foreign substances in the blood.

The purpose of the study is to assess the safety and effectiveness of nipocalimab compared to placebo (a drug like substance that has no therapeutic effect) in the treatment of pregnant individuals at risk of developing severe HDFN.

Not everyone in the study will receive nipocalimab. For every two participants who receive nipocalimab, one participant receives placebo. This is a double-blind study, which means that the participant and the study doctor/team will not know whether if you are receiving nipocalimab or placebo.

Who can participate?
This study will include pregnant individuals from 18 to 45 years old, with a gestational age of

(GA) Week 13 to 18 weeks at the start of study treatment, and who have a history of severe hemolytic disease of the fetus and newborn (HDFN) in a prior pregnancy.

What does the study involve?
The study consists of 4 periods:
- Screening period (up to 11 weeks): Pregnant individuals will be evaluated from gestational age (GA) Week 8 through GA Week 18 to confirm they can take part in the study. During this period, a test will be done to determine if the fetus is reactive to the pregnant individual's antibodies.
- Treatment period: Participants will be randomly (like a flip of coin) assigned to receive either nipocalimab or placebo in 2:1 ratio, which means for every 2 participants who receive nipocalimab, 1 participant receives placebo. Participants will be dosed intravenously on a weekly basis for up to 23 weeks, after which they will continue to have weekly visits until delivery (up to 3 weeks)
- Safety follow-up period up to 6 months for pregnant individual after delivery and up to 2years for the neonate/infant after birth.
Participants will undergo study assessments and tests, such as blood tests, vaginal tests, ultrasound (imaging test that uses sound waves to produce images within the body), questionnaires and other assessments for fetal monitoring. Newborns may receive light-therapy or may be transfused with donor blood to manage high bilirubin level. Blood samples will be taken at multiple timepoints throughout the study. The possible side effects of the study drug will be documented and monitored during the study.
The overall duration of the study will be up to 2 years and 6 months.

What are the possible benefits and risks of participating?
There is no established benefit to participants of this study. Based on scientific theory, taking nipocalimab may reduce the risk and severity of HDFN. However, this cannot be guaranteed because nipocalimab is still under investigation as a treatment.
If participants are assigned to the placebo group, they will not receive nipocalimab during this study.

Currently, severe HDFN is most commonly treated by injecting donor red blood cells into the fetus, a procedure called intrauterine transfusion. The study doctor will determine the need for an intrauterine transfusion, no matter if you are receiving nipocalimab or placebo.

Participants may experience some benefit from participation in the study that is not due to the study drug. However, they may benefit from regular medical visits and assessments which will monitor overall health of participants.

Participants may have side effects and risks related to nipocalimab or procedures used in this study. Some of them may be serious and may require treatment and/or additional testing. Problems that are not expected may arise and they may be life-threatening.

Based on the limited experience in healthy individuals and patients and our current understanding of how nipocalimab might work in the body, there are several types of side effects that might occur in people receiving nipocalimab. Potential risks in participants include infection, reduced effectiveness of routine vaccines, and activation of latent virus due to decreased serum IgG (a type of blood protein that protects the body from infections such as bacteria and viruses, and allergens) concentrations. Additionally, there are potential risks of lowering of albumin in blood, infusion reactions, interactions with other therapeutic drugs, increase in cholesterol levels and placental infarction (disruption of blood supply to a part of the placenta). There is a potential risk for low IgG in neonates/infants born to mothers who received nipocalimab during pregnancy.

The participant information sheet and informed consent form, which will be signed by each participant who agrees to join the study, includes a detailed section outlining the known risks of participating in the study.

Not all possible side effects and risks related to nipocalimab are known at this moment. During the study, the sponsor may learn new information about nipocalimab. The study doctor will tell participants as soon as possible about any new information that might make them change their mind about being in the study, such as new risks.

To minimize the risk associated with taking part in the study, participants are frequently asked about any side effects and other medical events they experience. Participants are instructed to report any such events to the study doctor who will provide appropriate medical care. Any serious side effects that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team.

There are no costs to participants to be in the study. The sponsor will pay for the study drug, tests and procedures that are part of the study. The participant will receive reasonable reimbursement for study-related costs (e.g., travel/parking costs).

Where is the study run from?
Janssen-Cilag International NV is the sponsor for this study. The study will be run at multiple healthcare locations both within the UK and around the world.

When is the study starting and how long is it expected to run for?
October 2023 to July 2029

Who is funding the study?
Janssen Research & Development, LLC

Who is the main contact?
medinfo@its.jnj.com

Contact information

Type(s)
Scientific

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Clinical Trials Information System (CTIS)
2022-502629-16

Integrated Research Application System (IRAS)
1008016

ClinicalTrials.gov (NCT)
NCT05912517

Protocol serial number
80202135EBF3001, IRAS 1008016, CPMS 51209

Study information

Scientific Title
A phase 3 randomized, placebo-controlled, double-blind, multicenter study to evaluate the efficacy and safety of nipocalimab in pregnancies at risk for severe hemolytic disease of the fetus and newborn (HDFN)

Acronym
AZALEA

Study objectives
Main/Primary objectives:
1. To evaluate how effective nipocalimab is as compared to placebo on reducing the risk of fetal anemia with live neonates in pregnant participants at risk for severe hemolytic disease of the fetus and newborn (HDFN)

Secondary objectives:
1. To evaluate the effectiveness of nipocalimab compared with placebo:
2. in reducing the severity of HDFN in pregnant participants and their neonates/infants who are at risk for severe HDFN. The severity of HDFN will be measured using a severity index from 1 to 5 (1 = minimal or none, 2 = mild, 3 = moderate, 4 = severe, and 5 = fatal)
3. on delaying the onset of severe HDFN in pregnant participants who are at risk for severe HDFN
4. on reducing the risk of death and occurrence of HDFN in neonates born to pregnant individuals who are at risk for severe HDFN
5. on fetal HDFN management and outcomes in pregnant participants who are at risk for severe HDFN
6. on neonatal HDFN management and other outcomes of HDFN in neonates/infants of

pregnant participants who are at risk for severe HDFN
7. To evaluate the safety of nipocalimab compared with placebo in pregnant participants who are at risk for severe HDFN and pregnancy outcomes
8. To evaluate the safety of neonates/infants born to nipocalimab-treated pregnant individuals compared with neonates/infants born to pregnant individuals who received placebo
9. To evaluate the impact of nipocalimab on patient and caregiver-reported outcomes in participants who are at risk for severe HDFN and their neonates/infants

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/11/2023, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8357; Edgbaston.rec@hra.nhs.uk), ref: 23/WM/0223

Study design
Randomized placebo-controlled double-blind trial

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Hemolytic disease of fetus and newborn (HDFN)

Interventions
The total duration of this study is up to 135 weeks which includes an up to 9-week screening period, an up to 23-week treatment period, and a safety follow-up period of up to 6 months for the pregnant individual and up to 2 years for the baby after birth. At the beginning of the treatment period, participants will be randomly (like a flip of a coin) divided into one of two treatment groups:
Group 1: receive nipocalimab intravenously (IV) once weekly (qw) from randomization through gestational age (GA) Week 35.
Group 2: receive matching placebo IV qw from randomization through GA Week 35.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Nipocalimab

Primary outcome(s)
Percentage of pregnancies that did not result in fetal loss, IUT, hydrops fetalis, or neonatal death (during the neonatal period) will be reported. Hydrops fetalis is defined as the presence of greater than or equal to (>=)2 abnormal fluid collections in the fetus or neonate, such as ascites,

pleural effusions, pericardial effusion, and generalized skin edema (skin thickness greater (>)5 millimeter (mm). PMA is the time elapsed between the first day of the last menstrual period and birth (gestational age) plus the time elapsed after birth (chronological age).

Key secondary outcome(s))

1. Number of Participants With Hemolytic Disease of the Fetus and Newborn (HDFN) by Severity. The severity of HDFN is defined as: 5 (fatal): fetal or neonatal death due to any reason; 4 (severe): hydrops fetalis (in fetus or newborn) or receiving IUT during pregnancy as a result of HDFN but not 5 (fatal); 3 (moderate): neonatal exchange transfusions received as a result of HDFN related hemolysis and jaundice but not 4 (severe) or 5 (fatal); 2 (mild): neonatal simple transfusions received due to HDFN after birth, with or without phototherapy, but not 3 (moderate), 4 (severe), or 5 (fatal); and 1 (minimal or none): not in 2 (mild), 3 (moderate), 4 (severe), or 5 (fatal) as described above. Here database lock implies the last participant has given birth or terminated their pregnancy, completed the Week 4 visit after delivery, and whose neonate has also completed the Week 4 visit (or 41 weeks PMA, whichever is later) or died prior to this timepoint.
2. Time to First Occurrence of IUT or Hydrops Fetalis.
3. Neonatal Mortality and Morbidity Index (NMMI) in Liveborn Neonates. The NMMI will be assessed with the following categories: fatal: fetal/neonatal death; major morbidity: any of intraventricular hemorrhage grade 3/4, seizures, hypoxic-ischemic encephalopathy, necrotizing enterocolitis stage 2/3, respiratory distress syndrome requiring mechanical ventilation, bronchopulmonary dysplasia requiring oxygen support, or persistent pulmonary hypertension; Minor morbidity: anemia requiring simple transfusion, hyperbilirubinemia requiring an exchange transfusion, hypotension requiring treatment, intraventricular hemorrhage grade 1/2, necrotizing enterocolitis stage 1, or respiratory distress syndrome not requiring mechanical ventilation; None: no major or minor morbidities described above. Hyperbilirubinemia requiring phototherapy will be classified in this category.
4. Number of IUT's Received During the Pregnancy.
5. Percentage of Pregnancies With Fetal Loss.
6. Percentage of Pregnancies With Fetal or Neonatal Death. Percentage of pregnancies with fetal or neonatal death (through the neonatal period) as a result of HDFN will be reported.
7. Percentage of Pregnancies With Hydrops Fetalis. Hydrops fetalis is defined as the presence of >=2 abnormal fluid collections in the fetus or neonate, such as ascites, pleural effusions, pericardial effusion, and generalized skin edema (skin thickness >5 mm).
8. Percentage of Pregnancies Receiving IUT During Pregnancy.
9. Gestational Age (GA) at First IUT.
10. Percentage of Pregnancies Receiving >1 IUT During Pregnancy.
11. Percentage of Pregnancies Receiving IUT or HDFN Resulting in Fetal Demise (Less Than) <GA Week 20.
12. Gestational Age at Delivery.
13. Percentage of Pregnancies With Neonatal Death Through the Neonatal Period.
14. Percentage of Liveborn Neonates With HDFN-related Morbidities Other Than Anemia and Hyperbilirubinemia or Jaundice.
15. Absolute Weight of Liveborn Neonates or Infants
16. Change From Baseline in Weight of Liveborn Neonates or Infants.
17. Liveborn Neonates Length of Stay in Neonatal Intensive Care Unit.
18. Percentage of Liveborn Neonates Receiving Exchange Transfusions for HDFN.
19. Number of Neonatal Exchange Transfusions per Liveborn Neonate.
20. Percentage of Liveborn Neonates or Infants with Simple Transfusions for HDFN. Percentage of liveborn neonates or infants with simple transfusions for HDFN through the neonatal period (for the first database lock) or 12 weeks (for the second database lock) after birth will be

reported.
21. Number of Simple Transfusions for HDFN per Liveborn Neonate or Infant. Number of simple transfusions for HDFN per liveborn neonate or infant through the neonatal period (for the first database lock) or 12 weeks (for the second database lock) after birth will be reported.
22. Percentage of Liveborn Neonates With Hyperbilirubinemia Treated With Phototherapy.
23. Number of Days of Phototherapy Received for Hyperbilirubinemia per Liveborn Neonate.
24. Percentage of Liveborn Neonates or Infants Receiving Intravenous Immunoglobulin (IVIg) for HDFN Treatment.
25. Number of Maternal Deaths.
26. Number of Participants with Adverse Events (AEs). Number of participants with AEs, serious adverse events, and AEs of special interest (AESIs), AE's leading to discontinuations, infections, serious infections, infusion reactions, and hypersensitivity reactions will be reported. Treatment-emergent adverse events associated with the following situations are considered as AESIs: hypoalbuminemia, clinically significant bleeding with a corresponding placental finding on ultrasound, maternal infections that led to clinically significant morbidities or mortalities in fetus or neonates, Infections that are severe or require intravenous (IV) anti-infective or operative or invasive intervention in maternal participants or neonates or infants, and infants with hypogammaglobulinemia.
27. Number of Maternal Pregnancy Complications.
28. Number of IUT Related complications.
29. Percentage of Pregnancies With Caesarean Delivery, Preterm Birth, Fetal Growth, and Preeclampsia. Percentage of pregnancies with caesarean delivery, caesarean delivery due to IUT complications, preterm birth <GA week 28, preterm birth <GA week 32, preterm birth <GA week 34, preterm birth <GA week 37, fetal growth restriction, and preeclampsia will be reported.
30. Percentage of Liveborn Neonates or Infants Who Died.
31. Percentage of Liveborn Neonates or Infants With AEs. Percentage of liveborn neonates or infants with AEs, SAEs, AESIs, infections, serious infections will be reported. An AE is any untoward medical occurrence in a clinical study participant administered a pharmaceutical (investigational or non-investigational) product. Any event requiring hospitalization (or prolongation of hospitalization) that occurs during participation in the study must be reported as an SAE.
32. Percentage of Liveborn Neonates or Infants Receiving IVIg for Non-HDFN Indications.
33. Percentage of Liveborn Neonates or Infants With Abnormal Hearing.
34. Bayley Scales of Infant Development and Toddler Development. The Bayley Scales of infant development is considered the standard assessment of early child development and includes cognition, language, motor skills, social emotional, and adaptive behaviour will be reported. The Bayley Scales (3rd edition) are reference standards that measure infant and toddler development in five areas: cognition, language, motor skills, social-emotional and adaptive behaviour. The cognition, language and motor skills scales are directly administered to the infant, while social-emotional, and adaptive behaviour scales are caregiver questionnaires. The scores are standardized using norm reference samples with representative demographics and age adjusted for prematurity. Higher scores in the Bayley Scales indicate better outcomes.
35. Change From Baseline in Generalized Anxiety Disorder 7-Item (GAD7) Over time During Pregnancy and Postpartum. The GAD-7 scale is a self-administered questionnaire designed to measure anxiety. The recall period for all items is the past 2 weeks. Responses to all items are rated on a 4-point Likert scale ranging from 0 “not at all” to 3 “nearly every day”. The total score ranges from 0 to 21, with higher scores indicating higher severity of anxiety symptoms.
36. Change From Baseline in Short Form 36 Version 2 (SF-36v2) Acute Form Domain Score. The SF-36 version 2 acute is a self-administered, 36-item questionnaire measuring health-related quality of life and includes 8 domains that measure physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality social functioning, role limitations due to emotional problems, and mental health. The 8 domains can be aggregated into 2

summary scales that reflect physical and mental health: a physical component summary and a mental component summary. Responses to all items are rated on a 3, 5, or 6-point Likert scale, with higher scores indicating better health status.
37. Change From Baseline in EuroQol Five-dimension Questionnaire (EQ-5D-5L) Visual Analogue Scale (VAS) Score. The EQ-5D descriptive system is comprised of 5 items across the following 5 dimensions: mobility, self-care, usual activities, pain or discomfort and anxiety or depression. The EQ-5D-5L uses a 5-point Likert response scale ranging from “no problems” to “extreme problems”, with higher scores indicating better quality of life. EQ-5D-5L consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ-VAS). EQ-VAS score ranges from 0 to 100, where 0 = worst imaginable health state and 100 = best imaginable health state. Higher score indicates good health state.
38. Change From Baseline in EuroQol 5-Dimension Descriptive (EQ-5D) Index Score. The EQ-5D descriptive system is comprised of 5 items across the following 5 dimensions: mobility, self-care, usual activities, pain or discomfort and anxiety or depression. The EQ 5D-5L descriptive system uses a 5-point Likert response scale ranging from “no problems” to “extreme problems”, with higher scores indicating better quality of life.
39. Infant Health-Related Quality of Life Instrument (IQI) Score for Neonate or Infant Overtime. The IQI consists of 7 health attributes including sleeping, feeding, breathing, stooling or poo, mood, skin, and interaction. Responses to all items are rated on a 4-point Likert scale, with higher scores indicating better quality of life.

Completion date
10/07/2029

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/07/2025:
1. Pregnant and an estimated gestational age (GA) (based on ultrasound dating) from Week 13 and 0/7 days to 18 weeks and 6/7 days at randomisation
2. History of severe Hemolytic Disease of the Fetus and Newborn (HDFN) in a prior pregnancy defined as:
2.1. documented fetal anemia as result of HDFN or fetal hydrops as result of HDFN or received greater than or equal to (>=)1 IUT as a result of HDFN or
2.2. 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 >=4; other >=16) and evidence of an antigen-positive fetus
3. During the current pregnancy, presence of maternal alloantibody to RhD, Rhc, RhE, or RhC antigen with titers above the critical level (anti-Kell >= 4; other >=16) based on the designated central lab results at screening
4. Evidence of antigen-positivity corresponding to the current maternal alloantibody (RhD, Kell, Rhc, RhE, or RhC) confirmed by non-invasive antigen cell-free fetal DNA (cffDNA) performed at the central laboratory.
5. Have screening laboratory values within the study protocol-specified parameters:
5.1. albumin >= lower limit of normal (LLN)
5.2. alanine transaminase (AST) less than or equal to (<=) 2 × upper limit of normal (ULN)
5.3. alanine transaminase (ALT) <=2 × ULN
5.4. creatinine <=0.8 milligrams per deciliter (mg/dL), SI: <=70.7 micromole per liter (µmol/L), and

Serum total immunoglobulins G (IgG) ≥ 600 mg/dL SI: >=6 g/L
6. Medically stable on the basis of physical examination, medical history, vitalsigns, 12-lead ECG, and clinical laboratory tests performed at screening

Previous inclusion criteria:
1. Pregnant and an estimated gestational age (GA) (based on ultrasound dating) from Week 13 and 0/7 days to Week 16 and 6/7 days at randomization
2. History of severe Hemolytic Disease of the Fetus and Newborn (HDFN) in a prior pregnancy defined as:
2.1. documented fetal anemia, or received greater than or equal to (>=)1 IUT as a result of HDFN or
2.2. 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 >=4; other >=16) and evidence of an antigen-positive fetus
3. During the current pregnancy, presence of maternal alloantibody to RhD, Rhc, RhE, or RhC antigen with titers above the critical level (anti-Kell >= 4; other >=16) based on the designated central lab results at screening
4. Evidence of antigen-positivity corresponding to the current maternal alloantibody (RhD, Kell, Rhc, RhE, or RhC) confirmed by non-invasive antigen cell-free fetal DNA (cffDNA) performed at the central laboratory.
5. Have screening laboratory values within the study protocol-specified parameters:
5.1. albumin, >=2.6 grams (g) per deciliter (g/dL), international system (SI): >=26 gram per liter (g /L);
5.2. alanine transaminase (AST) less than or equal to (<=) 2 × upper limit of normal (ULN);
5.3. alanine transaminase (ALT) <=2 × ULN
5.4. creatinine <=0.8 milligrams per deciliter (mg/dL), SI: <=70.7 micromole per liter (µmol/L), and Serum total immunoglobulins G (IgG) ≥ 600 mg/dL SI: >=6 g/L
6. Otherwise healthy on the basis of physical examination, medical history, vital signs, 12-lead ECG, and clinical laboratory tests performed at screening.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Key exclusion criteria

1. Currently pregnant with a multiple gestation (twins or more)
2. Evidence of fetal anemia prior to randomization in the current pregnancy
3. Current uncontrolled hypertension
4. History of myocardial infarction, unstable ischemic heart disease, or stroke
5. Has any confirmed or suspected clinical immunodeficiency syndrome or has a family history of congenital or hereditary immunodeficiency unless confirmed absent in the participant
6. Has inflammatory or autoimmune diseases requiring immunosuppressive therapies that may jeopardize the safety of the participant
7. Currently has a malignancy or has a history of malignancy within 3 years before screening (with the exception of localized basal cell carcinoma and/or squamous cell carcinoma skin cancer that has been adequately treated with no evidence of recurrence for at least 3 months
8. Is currently receiving systemic corticosteroids or other immunosuppressants for disorders unrelated to the pregnancy
9. Has received or planning to receive plasmapheresis, immunoadsorption therapy, intravenous immunoglobulin (IVIg), or any immunoglobulin (Ig)G fragment crystallizable (Fc)-related protein therapeutics during the current pregnancy
10. Has a severe infection including opportunistic infections
11. Presence of abnormal (protocol-specified) hematologic laboratory values during screening
12. 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

Added 02/07/2025:
13. History of an unprovoked pulmonary embolism or history of recurrent deep vein thrombosis (DVT)

The above information was not intended to contain all considerations relevant to a participant's potential participation in a clinical trial.

Date of first enrolment
06/12/2023

Date of final enrolment
23/12/2026

Locations

Countries of recruitment
United Kingdom

England

Argentina

Australia

Austria

Belgium

Brazil

Canada

France

Germany

Ireland

Israel

Japan

Netherlands

New Zealand

Saudi Arabia

Spain

Sweden

Türkiye

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Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type
Industry

Funder Name
Janssen Research and Development

Alternative Name(s)
Janssen R&D, Janssen Research & Development, Janssen Research & Development, LLC, Janssen Research & Development LLC, Janssen Pharmaceutical Companies of Johnson & Johnson, Research & Development at Janssen, JRD, J&J PRD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinicaltrials/ transparency. As noted on this site, requests for access to the study data can be submitted through the Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary

Available on request