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A study of JNJ-77242113 for the treatment of participants with plaque psoriasis involving special areas (scalp, genital, and/or palms of hands and the soles of the feet)

Submission date
17/08/2023

Recruitment status
No longer recruiting

Registration date
23/10/2023

Overall study status
Ongoing

Last Edited
25/04/2025

Condition category
Skin and Connective Tissue Diseases

[_] 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
Plaque psoriasis is a skin disease that causes red, scaly, and sometimes painful and itchy patches on the skin.
Drugs that prevent interleukin IL-23* from binding to its receptor** may be an effective way to disease control. JNJ-77242113 is designed to target IL-23 receptor and block IL-23 from binding to it.
(*A specific type of protein involved in inflammation.)
(**A protein that binds to specific molecule.)
The purpose of this study is to see how effective JNJ-77242113 is in participants with plaque psoriasis involving special areas (scalp, genital, and/or palms of the hands and the soles of the feet).
Participants will receive JNJ-77242113 or placebo in a 2:1 ratio which means in every 2 participants who receive JNJ-77242113, 1 will receive placebo. JNJ-77242113 will be administered in all treatment groups (JNJ-77242113, placebo). This is a double-blind study, which means participant, caregiver, and study doctor will not know whether the participants are receiving JNJ-77242113 or placebo.

Who can participate?
Participants aged 18 years or older (in the UK) and aged 12 years or older (countries other than UK) with plaque psoriasis involving special areas (scalp, genital, and/or palms of the hands and the soles of the feet).

What does the study involve?
The study will be conducted in 3 periods:
1. Screening period (5 weeks)
2. Double-blind (156 weeks) treatment period: Participants will be randomly (like flip of a coin) divided to 2 groups:
Group 1: JNJ-77242113 orally from Week 0 through Week 156.

Group 2: Matching placebo of JNJ-77242113 orally from Week 0 through Week 16 and thereafter, JNJ-77242113 orally through Week 156.
Participants will undergo study assessments and tests, such as questionnaires, blood tests, vital signs, and physical exams. Blood samples will be taken at multiple timepoints to understand how the body responds to the study drug.
Follow-up period (4 weeks): Participants will be monitored for their health after the last dose of study drug until the study ends.
All side effects will be recorded until the study ends. The total study duration is approximately 3 years and 2 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 JNJ-77242113 may reduce plaque psoriasis (red, scaly, itchy patches on the skin). However, this cannot be guaranteed because JNJ-77242113 is still under investigation as a treatment and it is not known whether JNJ-77242113 will work.
If participants are put into the placebo treatment group, they will not receive JNJ-77242113 up to Week 16. Participants will start receiving JNJ-77242113 from Week 16 through Week 156 during this study.
Participants may experience some benefit from participation in the study that is not due to receiving JNJ-77242113, but due to regular visits and assessments monitoring overall health.
Participation may help other people with plaque psoriasis in the future.
Participants may have side effects from the drugs or procedures used in this study that may be mild to severe and even life-threatening, and they can vary from person to person. Potential risks include hypersensitivity reactions, anti-drug antibody production, and infection. Skin biopsy (optional procedure) may cause mild bleeding, pain, discomfort, scarring, discoloration, and infection. The participant information sheet and informed consent form, which will be signed by every participant agreeing to participate in the study, includes a detailed section outlining the known risks of participating in the study.
Not all possible side effects related to JNJ-77242113 are known at this moment. During the study, the sponsor may learn new information about JNJ-77242113. 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 reviewed for any side effects and other medical events. Participants are educated 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 and tests 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?
August 2023 to June 2027

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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Additional identifiers

EudraCT/CTIS number
2023-505122-34

IRAS number
1008238

ClinicalTrials.gov number
NCT06095102

Secondary identifying numbers
77242113PSO3003, IRAS 1008238, CPMS 57585

Study information

Scientific Title
A Phase III multicenter, randomized double-blind, placebo-controlled study to evaluate the efficacy and safety of JNJ-77242113 for the treatment of participants with plaque psoriasis involving special areas

Acronym
ICONIC-TOTAL

Study objectives
Main objectives
1. To evaluate the effectiveness of JNJ-77242113 in participants with plaque psoriasis involving special areas.

Secondary objectives
1. To evaluate the effectiveness (in general psoriasis and special area psoriasis) of JNJ-77242113 in participants with plaque psoriasis involving special areas.
2. To evaluate how effective JNJ-77242113 is on patient-related outcomes (PROs) in participants with plaque psoriasis involving special areas.
3. To assess the safety, tolerability, and effect of JNJ-77242113 in participants with plaque psoriasis involving special areas.
4. To further evaluate the effect of JNJ-77242113 on PROs in participants with plaque psoriasis involving special areas.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/10/2023, North West – Liverpool Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8118; liverpoolcentral.rec@hra.nhs.uk), ref: 23/NW/0268

Study design
Randomized placebo-controlled double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Plaque psoriasis

Interventions
The total duration of this study is up to 165 weeks, which includes an up to 5-week screening period, a 156-week treatment period, and a 4-week safety follow-up period. 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 JNJ-77242113 orally from Week 0 through Week 156
Group 2: receive placebo from Week 0 through Week 16 and thereafter will receive JNJ-77242113 from Week 16 through Week 156.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic, Pharmacogenomic

Phase
Phase III

Drug/device/biological/vaccine name(s)
JNJ-77242113

Primary outcome measure
Percentage of participants achieving an Investigator's Global Assessment (IGA) Score of 0 or 1 and Greater Than or Equal to (>=) 2 Grade Improvement from Baseline at Week 16. The IGA documents the investigator's assessment of the participant's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4).

Secondary outcome measures
1. Percentage of participants achieving Scalp-specific Investigator Global Assessment (ss-IGA) Score of 0 or 1 at Week 16. The ss-IGA instrument is used to evaluate the disease severity of scalp psoriasis. The lesions are assessed in terms of the clinical signs of redness, thickness, and scaliness which are scored as: absence of disease (0), very mild disease (1), mild disease (2), moderate disease (3), and severe disease (4).
2. Percentage of participants achieving Psoriasis Scalp Severity Index (PSSI) 90 at Week 16. The PSSI is a scalp-specific modification of the PASI based on the extent of involvement and the severity of erythema, infiltration, and desquamation. Involvement and severity of psoriasis on the PSSI is scored by physicians on a scale from 0 to 72, where 0 = no psoriasis and higher scores indicate more severe disease.
3. Percentage of participants achieving a Static Physician’s Global Assessment of Genitalia (sPGA-G) Score of 0 or 1 at Week 16. The sPGA-G is a 6-point scale to assess the severity of genital psoriasis at a given time point. The sPGA-G evaluates erythema, plaque elevation, and scale of genital psoriatic lesions. The severity of genital psoriasis is assessed as clear (0), minimal (1), mild (2), moderate (3), severe (4), and very severe (5).
4. Percentage of participants achieving a Physician’s Global Assessment of Hands and Feet (hf-PGA) Score of 0 or 1 at Week 16. The hf-PGA assesses the severity of hand and foot psoriasis using a 5-point scale to score the plaques on the hands and feet as: clear (0), almost clear (1), mild (2), moderate (3), and severe (4).
5. Percentage of participants achieving Psoriasis Symptom and Sign Diary (PSSD) Symptoms Score of 0 at Week 16. The PSSD includes a patient-reported outcome (PRO) questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
6. Percentage of participants achieving >=4 point improvement from baseline in PSSD itch score at Week 16. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking,

scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
7. Percentage of participants achieving Genital Psoriasis Sexual Frequency Questionnaire (GenPs-SFQ) Item 2 score of 0 or 1 at Week 16. The GenPs-SFQ is a 2-item participant-reported instrument used to assess the impact of genital psoriasis on the frequency of sexual activity in the last 7 days. Item 1 assesses the overall frequency of sexual activity in the last 7 days (none /zero, once, or 2 or more times), and item 2 assesses how frequently genital psoriasis symptoms have limited the frequency of sexual activity in the last 7 days (never [0], rarely [1], sometimes [2], often [3], or always [4]).
8. Percentage of participants achieving >=4-point improvement from baseline in Scalp Itch Numeric Rating Scale (NRS) Score at Week 16. The Scalp Itch NRS is a single-item instrument that evaluates the severity of scalp itch in adult and adolescent populations over the past 24 hours. The instrument uses an NRS score ranging from 0 (no scalp itch) to 10 (worst scalp itch imaginable).
9. Percentage of participants achieving >=4-point Improvement from Baseline in Genital Psoriasis Symptoms Scale (GPSS) Genital Itch NRS Score at Week 16. The GPSS is a participant-administered assessment of 8 symptoms: itch, pain, discomfort, stinging, burning, redness, scaling, and cracking. Each respondent is asked to answer the questions based on the psoriasis symptoms in his or her genital area. The overall severity for each individual genital psoriasis symptom is indicated by selecting the number from an NRS of 0 to 10 that best describes the worst level of each symptom in the genital area in the past 24 hours, ranging from 0 (no severity) to 10 (worst imaginable severity).
10. Number of participants with adverse events (AEs) up to week 165. An adverse event (AE) is any untoward medical event that occurs in a participant administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product.
11. Number of participants with serious adverse events (SAEs) up to week 165. An SAE is any AE which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product, or is medically important.
12. Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 90 Response at Week 16. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed and scored separately for erythema, induration, and scaling, which are each rated on a scale of 0 to 4 and extent of involvement on a scale of 0 to 6. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease.
13. Percentage of participants achieving PASI 75 Response at Week 16. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed and scored separately for erythema, induration, and scaling, which are each rated on a scale of 0 to 4 and extent of involvement on a scale of 0 to 6. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease.
14. Change from baseline in PASI Total Score at Week 16. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: head, trunk, upper, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 (none) to 4 (severe). The

PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease.
15. Change from baseline in BSA at Week 16. BSA is a commonly used measure of extent of skin disease. It is defined as the percentage of surface area of the body involved with the condition being assessed (that is, plaque psoriasis).
16. Percent change from baseline in Modified Nail Psoriasis Areas and Severity Index (mNAPSI) Score at Week 16. The mNAPSI is an index used for assessing and grading the severity of nail psoriasis. Each of the participant's ten fingernails are evaluated on 7 features. The first three features are each scored from 0 to 3 in severity and are (1) onycholysis and oil-drop dyschromia, (2) pitting, and (3) nail plate crumbling. The next four features are each scored 0 –absent or 1 – present, and are (1) leukonychia, (2) splinter hemorrhages, (3) nail bed hyperkeratosis, and (4) red spots in the lunula. The score ranges from 0-13 per nail, and 0-130 for all fingernails.
17. Percentage of participants achieving Fingernail Physician's Global Assessment (f-PGA) Score of 0 or 1 at Week 16. The f-PGA is used to evaluate the current status of a participant's fingernail psoriasis on a scale of 0 to 4 similar (clear [0], minimal [1], mild [2], moderate [3], or severe [4]). A higher score indicated severe disease.
18. Percentage of participants achieving an IGA Score of 0 at Week 16. The IGA documents the investigator's assessment of the participant's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4).
19. Percentage of participants achieving PSSD Symptom Score of 0 at Week 8. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
20. Change from baseline in PSSD Symptom Score at Week 16. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
21. Percentage of participants achieving >=4-point improvement from baseline in PSSD Itch Score at Week 4. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
22. Change from baseline in PSSD sign score at Week 16. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.

23. Percentage of participants achieving PSSD Sign Score of 0 at Week 16. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
24. Percentage of participants achieving a Dermatology Life Quality Index (DLQI) Score of 0 or 1 at Week 16. The DLQI is a dermatology-specific health-related quality of life (HRQoL) instrument designed to assess the impact of the disease on a participant's HRQoL. It is a 10-item questionnaire that assesses HRQoL over the past week and in addition to evaluating overall HRQoL, can be used to assess 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. The total score ranges from 0 to 30 with a higher score indicating greater impact on HRQoL.
25. Percentage of participants achieving Children's Dermatology Life Quality Index (CDLQI) score of 0 or 1 at Week 16. The CDLQI is a dermatology-specific quality of life (QoL) instrument designed to assess the impact of the disease on a child's QoL. The CDLQI, a 10-item questionnaire has 4-item response options and a recall period of 1 week. The CDLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0; the higher the score, the greater the impairment in QoL.
26. Change from baseline in Domain Scores of the Patient-reported Outcomes Measurement Information System-29 (PROMIS-29) Score at Week 16. The PROMIS-29 is a 29-item generic HRQoL instrument assessing 7 PROMIS domains (depression, anxiety, physical function, pain interference, fatigue, sleep disturbance, and ability to participate in social roles and activities) with 4 questions for each domain. These questions are ranked on a 5-point Likert scale. There is also a numerical rating scale that ranges from 0 (No pain) to 10 (Worst pain imaginable) for pain intensity. The raw domain scores are converted to standardized T-scores with a mean of 50 and a standard deviation of 10. Higher scores on anxiety, depression, fatigue, sleep disturbance, and pain interference indicate more severe symptoms. Higher scores on physical function and social participation indicate better health outcomes.
27. Change from baseline in Domain Scores of the Patient-reported Outcomes Measurement Information System-25 (PROMIS-25) Score at Week 16. The PROMIS-25 will be utilized in the adolescent population and is a 25-item generic HRQoL survey. Six PROMIS domains (physical function mobility, anxiety, depressive symptoms, fatigue, peer relationships, pain interference) are each assessed with 4 questions. There is also one 11-point rating scale for pain intensity. The instrument is designed for use in ages 8-17 years of age and can be self-administered.
28. Change from baseline in Palmoplantar Quality of Life Instrument (ppQLI) Score at Week 16. The ppQLI assesses the impact on patient quality of life due to palmoplantar psoriasis over the past month in adult and adolescent populations. Fifteen items evaluate hand functionality, pain, and social impact due to psoriasis. Fourteen items evaluate foot functionality, pain, and physical limitations due to psoriasis. All items use verbal rating scales ranging from 1 to 5. The ppQLI yields a score for hands, ranging from 15 to 80, and a score for feet, ranging from 14 to 70.
29. Change from baseline in Genital Psoriasis Symptoms Scale (GPSS) Total Score at Week 16. The GPSS is a participant-administered assessment of 8 symptoms: itch, pain, discomfort, stinging, burning, redness, scaling, and cracking. Each respondent is asked to answer the questions based on the psoriasis symptoms in his or her genital area. The overall severity for each individual genital psoriasis symptom is indicated by selecting the number from an NRS of 0 to 10 that best describes the worst level of each symptom in the genital area in the past 24 hours, ranging from 0 (no severity) to 10 (worst imaginable severity).

Overall study start date
15/08/2023

Completion date
14/06/2027

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Diagnosis of plaque psoriasis, with or without psoriatic arthritis (PsA), for at least 26 weeks prior to the first administration of study intervention
3. Candidate for phototherapy or systemic treatment for plaque psoriasis
4. Need to meet criteria:
4.1. Total body surface area (BSA) greater than or equal to (>=)1 percent (%) at screening and baseline,
4.2. and investigator global assessment (IGA) (overall) >=2 at screening and baseline
4.3. and at least one of the following: scalp-specific investigator global assessment (ss-IGA) score >=3 at screening and baseline, and/or
4.4. static physician's global assessment of genitalia (sPGA-G) >=3 at screening and baseline, and /or physician's global assessment of
hands and feet (hf-PGA) score >=3 at screening and baseline
5. Failed to respond to at least 1 topical therapy (example, corticosteroids, calcineurin inhibitors, and/or vitamin D analogs) used for treatment of psoriasis
6. Confirmation of plaque psoriasis in a non-special area (example, areas excluding scalp, genital, palmoplantar) at screening and baseline

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Nonplaque form of psoriasis (example, erythrodermic, guttate, or pustular)
2. Dermatoses other than plaque psoriasis (such as contact dermatitis) or palmoplantar pustulosis of the palmoplantar area (if hf-PGA >=3 at baseline)
3. Current drug-induced psoriasis (example, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium)
4. A current diagnosis or signs or symptoms of severe, progressive, or uncontrolled renal, liver, cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, haematologic,

rheumatologic, psychiatric, or metabolic disturbances
5. Known allergies, hypersensitivity, or intolerance to JNJ-77242113 or its excipients

Date of first enrolment
12/10/2023

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
Argentina

Canada

Germany

Hungary

Korea, South

Poland

Spain

Taiwan

Türkiye

United Kingdom

United States of America

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Sponsor type
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Website
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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

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Submission to regulatory authorities
5. Study results will be available to participants via the provision of a Plain Language Summary at the end of the study and in addition results will be published in the EudraCT database

Intention to publish date
10/07/2030

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