ISRCTN54453452 https://doi.org/10.1186/ISRCTN54453452

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
24/10/2025

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?
JanssenUKRegistryQueries@its.jnj.com

Contact information

Type(s)
Public, Scientific

Contact name
Dr . Medical Information and Product Information Enquiry

Contact details
50-100 Holmers Farm Way
High Wycombe
United Kingdom
HP12 4DP
+44 (0)800 731 8450 / 10494 567 444
JanssenUKRegistryQueries@its.jnj.com

Additional identifiers

Clinical Trials Information System (CTIS)
2023-505122-34

Integrated Research Application System (IRAS)
1008238

ClinicalTrials.gov (NCT)
NCT06095102

Protocol serial number
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

Study type(s)
Efficacy, Safety, Treatment

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

Phase
Phase III

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

Primary outcome(s)
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).

Key secondary outcome(s))

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).

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Argentina

Canada

Germany

Hungary

Korea, South

Poland

Spain

Taiwan

Türkiye

United States of America

Study participating centre
Centro Privado de Medicina Familiar
Jose Pedro Varela 3954
Buenos Aires
Argentina
C1417EYG

Study participating centre
CEDIC Centro de Investigaciones Clinicas
Avenida Santa Fe 1480
Caba
Argentina
C1060ABN

Study participating centre
Conexa Investigacion Clinica S.A.
Libertad 1213
Caba
Argentina
C1012AAY

Study participating centre
CIPREC
Arenales 1611 2 Piso

Ciudad Autonoma de Buenos Aires
Argentina
C1061AAS

Study participating centre
Hospital Central Militar Cirujano Mayor Dr Cosme Argerich
Av. Luis Maria Campos 726
Caba
Argentina
C1426BOS

Study participating centre
Instituto Medico de La Fundacion Estudios Clinicos
Italia 428
Rosario
Argentina
2000

Study participating centre
Skinsense Medical Research
411 2nd Avenue North
Saskatoon
Canada
S7K 2C1

Study participating centre
Innovaderm Research Inc.
3530 boulevard Saint-Laurent
Montreal
Canada
H2X 2V1

Study participating centre
York Dermatology Clinic and Research Centre
250 Harding Blvd. West
Richmond Hill
Canada
L4C 9M7

Study participating centre
Skin Centre for Dermatology
775 Monaghan Rd South
Peterborough
Canada
K9J 5K2

Study participating centre
Lynderm Research Inc.
25 Main Street Markham North
Markham
Canada
L3P 1X3

Study participating centre
Alberta DermaSurgery Centre
7609 - 109 Street NW
Edmonton
Canada
T6G 1C3

Study participating centre
Centre De Recherche Dermatologique Du Quebec Metropolitan
2880 Chemin Quatre-Bouregois
Quebec
Canada
G1V 4X7

Study participating centre
Medizinische Fakultat Carl Gustav Carus Technische Universitat Dresden
Fetscherstr. 74
Dresden
Germany
01307

Study participating centre
Universitaetsklinikum Frankfurt
Theodor-Stern-Kai 7
Frankfurt am Main
Germany
60590

Study participating centre
ISA - Interdisciplinary Study Association GmbH
Rankestrasse 33-34
Berlin
Germany
10789

Study participating centre
Klinische Forschung Schwerin GmbH
Friedrichstrasse 1
Schwerin
Germany
19055

Study participating centre
Hautarztpraxis
Annenstraße 151
Witten
Germany
58453

Study participating centre
Niesmann & Othlinghaus GbR
Alleestraße 80
Bochum
Germany
44793

Study participating centre
Rosenpark Research GmbH
Rheinstrasse 14
Darmstadt
Germany
64283

Study participating centre
Dermatologikum Hamburg Gmbh
Stephansplatz 5

Hamburg
Germany
20354

Study participating centre
CRS Clinical Research Services Berlin GmbH
Siemensdamm 65
Berlin
Germany
13627

Study participating centre
Obudai Egeszsegugyi Centrum Kft.
Lajos utca 74
Budapest
Hungary
1036

Study participating centre
Somogy Megyei Kaposi Mor Oktato Korhaz
Tallian Gyula utca 20-32
Kaposvar
Hungary
7400

Study participating centre
SZTE AOK Szent-Gyorgyi Albert Klinikai Kozpont, Borgyogyaszati és Allergologiai Klinika
Koranyi fasor 6.
Szeged
Hungary
6720

Study participating centre
Pecsi Tudomanyegyetem
Akac u. 1
Borgyogyaszati Klinika
Hungary
7632

Study participating centre
Derma-B Kft
Gyepusor utca 3. Fsz.
Debrecen
Hungary
4031

Study participating centre
Medmare Egeszsegugyi Es Szolgaltato Bt.
Jozsef Attila u.17,
Veszprem
Hungary
8200

Study participating centre
Debreceni Egyetem Klinikai Kozpont
Nagyerdei korut 98
Debrecen
Hungary
4032

Study participating centre
Allergo-Derm Bakos Kft.
Baross utca 20.
Szolnok
Hungary
5000

Study participating centre
Seoul National University Hospital
101 Daehak-ro, Jongno-gu
Seoul
Korea, South
03080

Study participating centre
Seoul National University Bundang Hospital
82, Gumi-ro 173beon-gil, Bundang-gu, Seongnam-si
Gyeonggi-do
Korea, South
13620

Study participating centre
Pusan National University Hospital
179 Gudeok-Ro, Seo-Gu
Busan
Korea, South
49241

Study participating centre
Konkuk University Medical Center
120-1 NeunGdong-ro, Gwangjin-Gu
Seoul
Korea, South
05030

Study participating centre
Korea University Guro Hospital
148, Gurodong-Ro
Seoul
Korea, South
152-703

Study participating centre
WroMedica I.Bielicka, A.Strzałkowska s.c.
ul. A. Mickiewicza 91
Wrocław
Poland
51-685

Study participating centre
DermoDent Centrum Medyczne Aldona Czajkowska Rafał Czajkowski s.c.
Tuberozy 3
Osielsko
Poland
86031

Study participating centre
Osteo-Medic s.c A. Racewicz, J Supronik
ul. Wiejska 81

Bialystok
Poland
15-351

Study participating centre
Dermed Centrum Medyczne Sp. z o.o
ul. Piotrkowska 48
Lodz
Poland
90-265

Study participating centre
Klinika Ambroziak Estederm Sp. z o.o
Sikorskiego 13/U1
Warszawa
Poland
02-758

Study participating centre
Lidia Rajzer - Specjalistyczny Gabinet Dermatologiczno-Kosmetyczny
Borkowska 29A/9
Krakow
Poland
30-438

Study participating centre
Przychodnia Specjalistyczna High-Med
27 Jana Kasprowicza
Warszawa
Poland
01-817

Study participating centre
Specjalistyczny gabinet dermatologiczny Aplikacyjno-Badawczy Marek Brzewski, Pawel Brzewski Spolka Cywilna
Zbozowa
Krakow
Poland
30-002

Study participating centre
Centrum Kliniczno Badawcze J. Brzezicki, B. Gornikiewicz-Brzezicka Lekarze Spolka Partnerska
Studzienna 35-36/A
Elblag
Poland
82-300

Study participating centre
Centrum Medyczne Promed
ul. Nad Struga 7
Krakow
Poland
31-411

Study participating centre
SOLUMED Centrum Medyczne
ul. Dąbrowskiego 77a (Budynek Nobel Tower)
Poznan
Poland
60-529

Study participating centre
Centrum Medyczne Oporow
ul. Ludwika Solskiego 4a/1
Wroclaw
Poland
52-416

Study participating centre
Specderm Poznańska sp. j.
ul. Prezydenta Ryszarda Kaczorowskiego 7 lok. 50 U
Bialystok
Poland
15-375

Study participating centre
DERMMEDICA Sp.z o.o.
ul. Zakrzowska 19 a

Wroclaw
Poland
51-318

Study participating centre
Clinical Research Center sp. z o.o MEDIC-R s.k.
ul. Poznanska 3 lok. 31
Poznan
Poland
60-848

Study participating centre
HOSP. UNIV. 12 DE OCTUBRE
Avenida de Cordoba, km 5,4
Madrid
Spain
28041

Study participating centre
HOSP. UNIV. I POLITECNI LA FE
Avda. Fernando Abril Martorell, 106
Valencia
Spain
46026

Study participating centre
HOSP. DE MANISES
Avenida de la Generalitat Valenciana 50
Manises
Spain
46940

Study participating centre
HOSP. UNIV. SAN CECILIO
Avenida del Conocimiento 33
Granada
Spain
18016

Study participating centre
HOSP. VIRGEN MACARENA
Avenida Doctor Fedriani, nº 3
Sevilla
Spain
41009

Study participating centre
HOSP. UNIV. GERMANS TRIAS I PUJOL
Carretera de Canyet s/n
Badalona
Spain
08916

Study participating centre
HOSP. SANT JOAN DE DEU
Passeig Sant Joan de Déu 2
Esplugues de Llobregat
Spain
08950

Study participating centre
HOSP. DEL MAR
Passeig Maritim, 25-29
Barcelona
Spain
08003

Study participating centre
National Taiwan University Hospital
No.1, Changde St., Zhongzheng Dist.
Taipei
Taiwan
10048

Study participating centre
Linkou Chang Gung Memorial Hospital
No.5 Fuxing street
Taoyuan
Taiwan
33382

Study participating centre
Kaohsiung Chang Gung Memorial Hospital
No. 123, DAPI Road, Niaosng District
Kaohsiung
Taiwan
83301

Study participating centre
National Taiwan University Hospital Hsin-Chu Branch
Room 57, 1F, No.25, Lane 442, Sec.1, Jingguo Rd.
Hsinchu
Taiwan
300

Study participating centre
Istanbul University Cerrahpasa Medical Faculty
Kocamustafapasa Cad. Cerrahpasa No: 53
Istanbul
Türkiye
34098

Study participating centre
Ondokuz Mayis University
Ondokuz Mayis Unv
Samsun
Türkiye
55270

Study participating centre
Karadeniz Teknik University Medical Faculty
Farabi cad.
Trabzon
Türkiye
61080

Study participating centre
Necmettin Erbakan University Meram Medical Faculty
Meram

Konya
Türkiye
42080

Study participating centre
Pamukkale University Medical Faculty
Camlaraltı, Kinikli Yerleskesi, Universite Cd. No:11
Denizli
Türkiye
20070

Study participating centre
Ankara Etlik Speciality Hospital
Varlık, Halil Sezai Erkut Cd. No:5
Ankara
Türkiye
06170

Study participating centre
Newcastle upon Tyne Hospitals NHS Foundation Trust
New Victoria Wing, Level 2, Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Study participating centre
Northwick Park Hospital
Watford Road
London
United Kingdom
HA1 3UJ

Study participating centre
Victoria Hospital
Phase 1, Level 2
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
Salford Royal Hospital
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Northshore Medical Group
9933 Woods Dr
Skokie
United States of America
60076

Study participating centre
Oregon Dermatology and Research Center
2565 NW Lovejoy
Portland
United States of America
97210

Study participating centre
Arlington Research Center, Inc.
711 East Lamar Boulevard, Ste 200
Arlington
United States of America
76011

Study participating centre
Center for Clinical Studies
451 North Texas Avenue
Webster
United States of America
77598

Study participating centre
Progressive Clinical Research
1973 N.W. Loop 410
San Antonio
United States of America
78213

Study participating centre
Skin Specialists
2802 Oak View Drive
Omaha
United States of America
68144

Study participating centre
Dermatology and Advanced Aesthetics
3635 Nelson Road
Lake Charles
United States of America
70605

Study participating centre
Optima Research
1039 Boardman-Canfield Road
Boardman
United States of America
44512

Study participating centre
Center for Clinical Studies
1401 Binz Street
Houston
United States of America
77004

Study participating centre
Austin Institute for Clinical Research
1601 E Pflugerville Pkwy

Pflugerville
United States of America
78660

Study participating centre
Minnesota Clinical Study Center
119-14th Street N.W.,
New Brighton
United States of America
55112

Study participating centre
MediSearch Clinical Trials
1427 Village Drive
Saint Joseph
United States of America
64506

Study participating centre
Frontier Derm Partners CRO, LLC
15906 Mill Creek Blvd
Mill Creek
United States of America
98012

Study participating centre
Windsor Dermatology
59 One Mile Rd Ext Ste G
East Windsor
United States of America
8520

Study participating centre
Dermatology Clinical Research Center of San Antonio
7810 Louis Pasteur Dr Ste 200
San Antonio
United States of America
78229

Study participating centre
FORCARE CLINICAL RESEARCH, INC.
15416 North Florida Avenue
Tampa
United States of America
33613

Study participating centre
Dawes Fretzin Clinical Research Group, LLC
7910 North Shadeland Avenue
Indianapolis
United States of America
46250

Study participating centre
Dundee Dermatology
1201 Water Tower Rd
West Dundee
United States of America
60118

Study participating centre
Indiana Clinical Trial Center
824 Edwards Drive
Plainfield
United States of America
46168

Study participating centre
Johnson Dermatology
5921 Riley Park Drive
Fort Smith
United States of America
72916

Study participating centre
Hamilton Research, LLC.
11800 Atlantis Place
Alpharetta
United States of America
30022

Study participating centre
University of Pittsburgh Medical Center
3601 5Th Ave
Pittsburgh
United States of America
15213

Study participating centre
Arlington Dermatology
5301 Keystone Ct.
Rolling Meadows
United States of America
60008

Study participating centre
Hamzavi Dermatology
2950 Keewahdin Road
Fort Gratiot
United States of America
48059

Study participating centre
Allcutis Research
138 Conant Street
Beverly
United States of America
01915

Study participating centre
California Dermatology & Clinical Research Institute
561 Saxony Place
Encinitas
United States of America
92024

Study participating centre
Center for Dermatology and Plastic Surgery
14301 N 87th St

Scottsdale
United States of America
85260

Study participating centre
Cope Family Medicine - Ogden Clinic
185 S 400 E
Bountiful
United States of America
84010

Study participating centre
DermAssociates, PC
15245 Shady Grove Road
Rockville
United States of America
20850

Study participating centre
Paddington Testing Co, Inc.
1845 Walnut Street
Philadelphia
United States of America
19103

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