ISRCTN21453767 https://doi.org/10.1186/ISRCTN21453767

A study of JNJ-77242113 in adolescent and adult participants with moderate to severe plaque psoriasis

Submission date
24/08/2023

Recruitment status
No longer recruiting

Registration date
08/11/2023

Overall study status
Ongoing

Last Edited
26/10/2026

Condition category
Skin and Connective Tissue Diseases

[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
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. The study drug, JNJ-77242113, is a medicine designed to target the 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 check the efficacy of JNJ-77242113 compared to placebo (looks like JNJ-77242113 but it does not contain any active medication) in participants with moderate to severe plaque psoriasis.

Who can participate?
Study includes participants 12 years or older with moderate to severe plaque psoriasis (in the UK, only participants 18 years or older will be recruited).

What does the study involve?
The study will be conducted in 3 periods:
1. Screening period (5 weeks): Participants will be screened to confirm if they can take part in the study.
2. Double-blind (156 weeks) treatment period: Both Adult and Adolescent participants will be divided into 2 arms to receive either JNJ-77242113 or placebo.
Adult:
Group 1: Participants will receive JNJ-77242113 orally from Weeks 0 through Week 24. At Week 24, psoriasis area and severity index (PASI) 75 responders or participants who achieve an investigator global assessment (IGA) score of 0 or 1 and have >=2-grade improvement from baseline will be re-randomized either to continue JNJ-77242113 orally or to placebo whereas PASI 75 and IGA 0 to 1 non-responders will continue to receive JNJ-77242113 through Week 52. Participants randomized to placebo will be retreated prior to Week 52 if they lose >=50% of their PASI score at Week 24. From Weeks 52 to 156, all participants will receive JNJ-77242113.

Group 2: Participants will receive JNJ-77242113 matching placebo from Weeks 0 to 16 and thereafter, JNJ-77242113 from Weeks 16 through 156.
Adolescent:
Group 1: Participants will receive JNJ-77242113 orally from Weeks 0 through 156
Group 2: Participants will receive JNJ-77242113 matching placebo from Weeks 0 to 16 and thereafter JNJ-77242113 from Weeks 16 through 156.
Participants will undergo study assessments and tests, such as questionnaire, blood tests, vital signs, and physical exams. The possible side effects of the study drug will be recorded till end of the study.
3. Follow-up period (4 weeks): Participants blood samples will be taken at multiple timepoints to understand how the body responds to study drug. will be monitored for their health after the last dose of study drug until the study ends.
All side effects will be recorded until 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. Some potential risks included 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 to participating in the study. For participants under the legal age of consent, parent (s) (preferably both if available or as per local requirement) or guardian will sign a separate inform consent form.
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 minimise 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 (Netherlands)

When is the study starting and how long is it expected to run for?
August 2023 to April 2027

Who is funding the study?
Janssen Research and Development LLC (USA)

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

Contact information

Type(s)
Public, Scientific

Contact name
None - Medical Information and Product Information Enquiry

Contact details
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Type(s)
Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06095115

Clinical Trials Information System (CTIS)
2023-505120-59

Integrated Research Application System (IRAS)
1008234

Central Portfolio Management System (CPMS)
57536

Protocol serial number
77242113PSO3001

Study information

Scientific Title
A phase 3 multicentre, randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of JNJ-77242113 for the treatment of participants with moderate to severe plaque psoriasis with randomised withdrawal and retreatment ICONIC-LEAD

Acronym
ICONIC-LEAD

Study objectives
Primary objective:
To assess the efficacy of JNJ-77242113 in participants with moderate to severe plaque psoriasis.

Secondary objectives:
1. To further evaluate efficacy (general and special area psoriasis) of JNJ-77242113 in participants with moderate to severe plaque psoriasis.
2. To evaluate the effect of JNJ-77242113 on patient reported outcomes (PROs) in participants with moderate to severe plaque psoriasis.
3. To evaluate the maintenance of efficacy of JNJ-77242113 compared with treatment withdrawal during the randomised withdrawal period.
4. To assess the safety and tolerability of JNJ-77242113 in participants with moderate to severe plaque psoriasis.
5. To evaluate long-term psoriasis efficacy of JNJ-77242113 in adolescent participants with moderate to severe plaque psoriasis

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/11/2023, London - Dulwich REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 115 8839435; dulwich.rec@hra.nhs.uk), ref: 23/LO/0790

Primary study design
Interventional

Study design
Interventional double-blind randomized placebo-controlled trial

Study type(s)
Efficacy, Safety, Treatment

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

Interventions

The study will be conducted in 3 periods:
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2. Double-blind (156 weeks) treatment period: Both Adult and Adolescent participants will be divided into 2 arms to receive either JNJ-77242113 or placebo.
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Participants will undergo study assessments and tests, such as questionnaire, blood tests, vital signs, and physical exams. The possible side effects of the study drug will be recorded till end of the study.
3. Follow-up period (4 weeks)

Intervention Type
Drug

Phase
Phase III

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

Primary outcome(s)
1. 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 to Week 16
2. Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 90 response at Week 16.

Key secondary outcome(s)
1. Percentage of participants achieving an IGA score of 0 at Week 16
2. Percentage of participants achieving PASI 75 response at Weeks 4 and 16
3. Percentage of participants achieving PASI 90 response at Week 8
4. Percentage of participants achieving PASI 100 response at Week 16
5. Percentage of participants achieving scalp-specific Investigator Global Assessment (ss-IGA) score of 0 or 1 and >=2 grade improvement baseline to Week 16
6. Percentage of participants achieving Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score of 0 at Weeks 8 and 16
7. Percentage of participants achieving Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score of 0 at Weeks 4 and 16

8. Percentage of participants achieving >=4-point improvement from baseline in PSSD Itch score to Weeks 4 and 16
9. Time to loss of PASI 75
10. Time to loss of PASI 90
11. Number of participants with treatment-emergent adverse events (AEs)
12. Number of Participants with Treatment-emergent Serious Adverse Events (SAEs)
13. Change from baseline in Body Surface Area (BSA) at Week 16
14. Change from baseline in PASI total score to Week 16
15. Percent improvement in PASI score from baseline to Week 16
16. Percentage of participants achieving a Static Physician's Global Assessment of Genitalia (sPGA-G) score of 0 or 1 and at least a 2-grade improvement in genital psoriasis from baseline to Week 16
17. Percentage of participants achieving a Physician's Global Assessment of Hands and Feet (hf-PGA) score of 0 or 1 and at least a 2-grade improvement at Week 16
18. Percent change from baseline in modified Nail Psoriasis Severity Index (mNAPSI) score at Week 16
19. Percent of participants achieving Fingernail Physician's Global Assessment (f-PGA) score of 0 or 1 from baseline to Week 16
20. Change from baseline in PSSD Symptom score to Week 16
21. Change from baseline in PSSD Sign score to Week 16
22. Percentage of participants achieving PSSD sign score of 0 at Week 16
23. Percentage of participants achieving Genital Psoriasis Sexual Frequency Questionnaire (GenPs-SFQ) Item 2 score of 0 or 1 at Week 16
24. Percentage of participants achieving Dermatology Life Quality Index (DLQI) score of 0 or 1 at Week 16
25. Change from baseline in total DLQI Score at Week 16
26. Change from baseline in domain scores of the Patient-reported Outcomes Measurement Information System-29 (PROMIS-29) score at Week 16
27. Percentage of participants achieving Children's Dermatology Life Quality Index (CDLQI) score of 0 or 1 at Week 16.
28. Change from baseline in CDLQI at Week 16.
29. Change from baseline in the domain scores of the PROMIS-25 Paediatric score at Week 16.
30. Percentage of participants achieving IGA score of 0 at Week 52
31. Percentage of participants achieving PASI 100 response at Week 52
32. Time to loss of IGA 0 to 1 response
33. Percentage of Adolescent Participants Achieving IGA Score of 0 or 1 and >=2 Improvement From Baseline to Week 52
34. Percentage of Adolescent Participants Achieving PASI 75 Response at Week 52
35. Percentage of Adolescent Participants Achieving PASI 90 Response at Week 52

Completion date
06/04/2027

Eligibility

Key inclusion criteria
1. Diagnosis of plaque psoriasis, with or without psoriatic arthritis, for at least 26 weeks prior to the first administration of study intervention
2. Total body surface area (BSA) greater than or equal to (>=)10 percent (%) at screening and baseline
3. Total psoriasis area and severity index (PASI) >=12 at screening and baseline

4. Total investigator global assessment (IGA) >=3 at screening and baseline
5. Candidate for phototherapy or systemic treatment for plaque psoriasis
6. A female participant of childbearing potential must have a negative highly sensitive serum pregnancy test beta-human chorionic gonadotropin (beta-hCG) at screening and a negative urine pregnancy test at Week 0 prior to administration of study intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
684

Key exclusion criteria
1. Non-plaque form of psoriasis (for example, erythrodermic, guttate, or pustular)
2. Current drug-induced psoriasis (for example, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium)
3. 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
4. Known allergies, hypersensitivity, or intolerance to JNJ-77242113 or its excipients
5. Major surgical procedures, (for example, requiring general anaesthesia) within 8 weeks before screening, or will not have fully recovered from a surgical procedure or has a surgical procedure planned during the time the participant is expected to participate in the study.

Date of first enrolment
01/12/2023

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
United Kingdom

Argentina

Australia

Canada

China

France

Germany

Hungary

Italy

Japan

Korea, South

Poland

Spain

Taiwan

Türkiye

United States of America

Study participating centre
Guy's and St Thomas's NHS Foundation Trust
Great Maze Pond
London
England
SE1 9RT

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
England
HA1 3UJ

Study participating centre

Chapel Allerton Hospital
Chapeltown Road
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England
LS7 4SA

Study participating centre
Salford Royal Hospital
Stott Lane
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M6 8HD

Study participating centre
Royal Berkshire Hospital
Craven Road
Reading
England
RG1 5AN

Sponsor information

Organisation
Janssen-Cilag International N.V.

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 Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary
Available on request