

Velocity: A study of JNJ-81241459 in participants with moderate to severe plaque psoriasis

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| Submission date 12/04/2024 | Recruitment status Stopped | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 06/06/2024 | Overall study status Stopped | <input type="checkbox"/> Protocol |
| Last Edited 23/07/2024 | Condition category Skin and Connective Tissue Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Plaque psoriasis is skin disease that causes dry, itchy, thick, and raised skin patches on skin. Drugs that prevent interleukin (IL)-17 or 23* from binding to its receptor** may be an effective way to disease control.

The study drug, JNJ- 81241459, is a medicine designed to inhibit the IL-17 binding to its receptor.

*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-81241459 is when compared to placebo (looks like JNJ-81241459 but it does not contain any active medication) in participants with moderate to severe plaque psoriasis.

Who can participate?

Study includes participants of 18 years or older with moderate to severe plaque psoriasis.

What does the study involve?

Study will be conducted in 3 periods:

1. Screening period (5 weeks)
2. Double-blind 12 weeks) treatment period: Participants will be randomly (like flip of a coin) divided into 5 groups (1:1:1:1:1) to receive JNJ-81241459 or placebo from Week 0 through Week 12.
 - Group 1: Participants will receive JNJ-81241459 Dose 1.
 - Group 2: Participants will receive JNJ-81241459 Dose 2.
 - Group 3: Participants will receive JNJ-81241459 Dose 3.
 - Group 4: Participants will receive JNJ-81241459 Dose 4.
 - Group 5: Participants will receive JNJ-81241459 matching placebo.
3. 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 study ends. The total study duration is approximately 6 months. Participants will undergo study assessments and tests, such as questionnaires, blood tests, vital signs, and physical exams. The possible side effects of the study drug will be recorded

till end of the study. Blood samples will be taken at multiple timepoints to understand how the body responds to study drug.

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-81241459 may reduce plaque psoriasis (red, scaly, itchy patches on the skin). However, this cannot be guaranteed because JNJ-81241459 is still under investigation as a treatment and it is not known whether JNJ-81241459 will work.

If participants are put into the placebo treatment group, they will not receive JNJ-81241459 and will only receive placebo during this study.

Participants may experience some benefit from participation in the study that is not due to receiving JNJ-81241459, 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, infection, malignancy, inflammatory bowel disease, suicidal ideation and behavior, cytopenia, reproductive risk and pregnancy, QTc Interval Prolongation, tablet size and swallowing difficulty/airway obstruction. 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.

Not all possible side effects related to JNJ-81241459 are known at this moment. During the study, the sponsor may learn new information about JNJ-81241459. 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 (Netherlands)

When is the study starting and how long is it expected to run for?

November 2023 to June 2025

Who is funding the study?

Janssen Research and Development LLC (USA)

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

Contact information

Type(s)
Scientific

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Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2023-508992-35

Integrated Research Application System (IRAS)
1009563

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
81241459PSO2001, IRAS 1009563, CPMS 59821

Study information

Scientific Title

A phase 2b multicenter, randomized, double-blind, placebo-controlled dose-ranging study to evaluate the efficacy and safety of JNJ-81241459 for the treatment of participants with moderate to severe plaque psoriasis

Acronym

Velocity

Study objectives

Primary objective:

To evaluate how effective is the JNJ-81241459 when compared with placebo in participants with moderate to severe plaque psoriasis.

Secondary objectives:

1. To further evaluate how effective is the JNJ-81241459 when compared with placebo in participants with moderate to severe plaque psoriasis.
2. To evaluate the effect of JNJ-81241459 compared with placebo on patient reported outcomes in participants with moderate to severe plaque psoriasis.
3. To evaluate the safety and tolerability of JNJ-81241459 compared with placebo in participants with moderate to severe plaque psoriasis.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 30/05/2024, East Midlands – Derby (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8154; derby.rec@hra.nhs.uk), ref: 24/EM/0100

Study design

Interventional double blind randomized placebo controlled trial

Primary study design

Interventional

Study type(s)

Safety, Efficacy

Health condition(s) or problem(s) studied

Plaque Psoriasis

Interventions

Study will be conducted in 3 periods:

1. Screening period (5 weeks)
2. Double-blind 12 weeks) treatment period: Participants will be randomly (like flip of a coin) divided into 5 groups (1:1:1:1:1) to receive JNJ-81241459 or placebo from Week 0 through Week 12.
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3. 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 study ends. The total study duration is approximately 6 months.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

JNJ-81241459

Primary outcome(s)

1. Percentage of Participants Achieving Psoriasis Area Severity Index (PASI) 75 Score at Week 12

Key secondary outcome(s)

1. Percentage of Participants Achieving PASI 90 at Week 12
2. Percentage of Participants Achieving PASI 100 at Week 12
3. Percentage of Participants Achieving an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) and a Greater Than or Equal to [\geq] 2 Grade Improvement From Baseline at Week 12
4. Percentage of Participants Achieving an IGA score of cleared (0) at Week 12
5. Change from Baseline in Body Surface Area (BSA) at Week 12
6. Change from baseline in PASI total score at Week 12
7. Percent Change from Baseline in PASI Total Score at Week 12
8. Percentage of Participants Achieving Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Score=0 at Week 12
9. Percentage of Participants Achieving PSSD sign score of 0 at Week 12
10. Percentage of Participants Achieving ≥ 4 -point improvement from baseline in PSSD Itch score at Week 12
11. Change from baseline in PSSD symptom score at Week 12
12. Change from baseline in PSSD sign score at Week 12
13. Percentage of Participants Achieving Dermatology Life Quality Index (DLQI) Score of 0 or 1 at Week 12
14. Change from baseline DLQI total score at Week 12
15. Number of Participants with Adverse Events (AEs)
16. Number of Participants with Serious Adverse Events (SAEs)

Completion date

02/06/2025

Reason abandoned (if study stopped)

Non-clinical findings

Eligibility

Key inclusion criteria

1. Be ≥ 18 years of age at screening, inclusive
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. Total body surface area (BSA) greater than or equal to (\geq)10 percent (%) at screening and baseline
4. Total Psoriasis area and severity index (PASI) ≥ 12 at screening and baseline
5. Total Investigator global assessment (IGA) ≥ 3 at screening and baseline
6. Candidate for phototherapy or systemic treatment for plaque Psoriasis

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 (eg, erythrodermic, guttate, or pustular)
2. Current drug-induced psoriasis (eg, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium)
3. Known allergies, hypersensitivity, or intolerance to JNJ-81241459 or its excipients (refer to the JNJ-81241459 IB)
4. Previously received JNJ-81241459
5. Experienced primary efficacy failure (no response within 12 weeks) or a clinical adverse event related to agents directly targeting interleukin 17 receptor (IL-17)

Date of first enrolment

01/09/2024

Date of final enrolment

13/01/2025

Locations**Countries of recruitment**

United Kingdom

Canada

France

Germany

Japan

Poland

Spain

Study participating centre

Whipps Cross University Hospital

Whipps Cross Road

Leytonstone

London

United Kingdom

E11 1NR

Study participating centre

Lakeside Healthcare Cottingham Road

1 Cottingham Road

Corby

United Kingdom

NN17 2UR

Study participating centre

Mid Yorkshire Teaching NHS Trust

Pinderfields Hospital

Aberford Road

Wakefield

United Kingdom

WF1 4DG

Study participating centre

Velocity Clinical Research

First Floor Apollo Centre

Desborough Road

High Wycombe

United Kingdom

HP11 2QW

Study participating centre

The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust

Queen Elizabeth Hospital

Gayton Road

King's Lynn

United Kingdom

PE30 4ET

Study participating centre

Velocity Clinical Research, North London

48e Percy Road, North Finchley, London

North Finchley

London

United Kingdom

N12 8BU

Study participating centre

Salford Royal NHS Foundation Trust

Stott Lane

Salford

United Kingdom

M6 8HD

Study participating centre

University Hospital Southampton NHS Foundation Trust

Southampton General Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

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 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, Data sharing statement to be made available at a later date