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

Submission date
12/04/2024

Recruitment status
Stopped

Registration date
06/06/2024

Overall study status
Stopped

Last Edited
23/07/2024

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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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Clinical Trials Information System (CTIS)
2023-508992-35

Integrated Research Application System (IRAS)
1009563

Central Portfolio Management System (CPMS)
59821

Protocol serial number
81241459PSO2001

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

Primary study design
Interventional

Study design
Interventional double blind randomized placebo controlled trial

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.
• Group 1: Participants will receive JNJ-81241459 Dose 1.
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• Group 3: Participants will receive JNJ-81241459 Dose 3.
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• 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.

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 [>=] 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 (>=)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
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London
United Kingdom
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Study participating centre
Lakeside Healthcare Cottingham Road
1 Cottingham Road
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NN17 2UR

Study participating centre
Mid Yorkshire Teaching NHS Trust
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WF1 4DG

Study participating centre
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Study participating centre

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Study participating centre
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Southampton General Hospital
Tremona Road
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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