

A study of the efficacy and safety of JNJ77242113 in biologic-experienced participants with active psoriatic arthritis

Submission date 30/11/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/01/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/02/2025	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Active psoriatic arthritis (PsA) is a chronic disease that causes joint pain and swelling. Patients may also have red patches on their skin. Psoriatic arthritis can affect any joint in the body, including fingers, toes, knees, and the spine. This can make it harder to move around and do everyday tasks. Drugs that prevent interleukin IL-23 (a specific type of protein involved in inflammation) from binding to its receptor (a protein that binds to specific molecules) may be an effective way to disease control. The study drug, icotrokinra, is a medicine designed to target the IL-23 receptor and block IL-23 from binding to it. In this study, researchers want to check how well icotrokinra works when compared to placebo (does not contain any active medication) in participants with PsA.

Who can participate?

Participants aged 18 years or older with PsA can participate.

What does the study involve?

This study lasts for 52 weeks, with an additional 52-week extension. At the start, participants will be randomly assigned to one of three groups: Group I will receive Dose 1 of icotrokinra daily, Group II will receive Dose 2 daily, and Group III will receive a placebo daily. At Week 16, participants will switch to either Dose 1 or Dose 2 of icotrokinra. The study includes a screening period of up to 5 weeks, a placebo-controlled period of up to 16 weeks, a blinded active-treatment period of up to 36 weeks, and a safety follow-up visit 4 weeks after the last dose. Participants who complete the main study can join the 52-week extension, which includes 48 weeks of active treatment and 4 weeks of safety follow-up. Safety assessments will monitor adverse events, vital signs, questionnaires, and blood tests, with all side effects recorded until the study ends, approximately 2 years in total.

What are the possible benefits and risks of participating?

There is no established benefit to participants of this study. Based on scientific theory, taking icotrokinra may improve active psoriatic arthritis. However, this cannot be guaranteed because icotrokinra is still under investigation as a treatment, and it is not known whether active

psoriatic arthritis will work. In addition, if participants are put into the placebo treatment group, they will not receive icotrokinra. At Week 16, participants assigned to the placebo group will cross over to receive icotrokinra Dose 1 or Dose 2 once daily.

Participants may experience some benefit from participation in the study that is not due to receiving study drug, but due to regular visits and assessments monitoring overall health.

Participation may help other people with psoriatic arthritis (PsA) 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. 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 (inappropriate or exaggerated response to an antigen or an allergen), anti-drug antibody production, and infection. The participant information sheet and informed consent study drug or placebo 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 and risks related to icotrokinra are known at this moment. During the study, the sponsor may learn new information about icotrokinra. The study doctor will tell participants as soon as possible about any new information that might make them change their minds 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 their 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?

Midlands Partnership NHS Foundation Trust, UK

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

November 2024 to October 2028

Who is funding the study?

Janssen-Cilag International N.V.

Who is the main contact?

JanssenUKRegistryQueries@its.jnj.com

Contact information

Type(s)

Public, Scientific

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Additional identifiers

EudraCT/CTIS number

2024-517284-23

IRAS number

1010955

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

77242113PSA3002, CPMS 64272

Study information

Scientific Title

A Phase III, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of JNJ-77242113 for the treatment of biologic-experienced participants with active psoriatic arthritis

Acronym

ICONIC-PsA 2

Study objectives

Primary objective:

To evaluate how well icotrokinra (JNJ-77242113) works at Dose 1 and Dose 2 doses compared to a placebo in reducing psoriatic arthritis (PsA) symptoms at Week 16.

Secondary objectives:

To evaluate the following for icotrokinra compared to a placebo in participants with PsA at

Week 16:

1. Efficacy in improving skin symptoms, like rashes or patches.
2. Efficacy in reducing joint pain, swelling, and other symptoms of PsA.
3. Efficacy in improving physical function, such as movement and daily activities.
4. Efficacy in improving health-related quality of life (HRQoL).
5. Efficacy in reducing enthesitis (inflammation where tendons or ligaments attach to bone) and dactylitis (swelling of fingers or toes).
6. To further evaluate how well icotrokinra works compared to a placebo in people with PsA.
7. Efficacy in reducing fatigue symptoms.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 08/01/2025, Wales REC 5 (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 940910; Wales. REC5@wales.nhs.uk), ref: 24/LO/0913

Study design

Interventional double-blind randomized parallel group placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

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

Arthritis, Psoriatic

Interventions

This study is a 52-week main study with a 52-week blinded long-term extension (LTE). At Week 0, participants will be randomly (by chance) assigned to one of the 3 treatment arms: Group I: icotrokinra Dose 1, Group II: icotrokinra Dose 2, Group III: Placebo. At Week 16, participants will cross over to receive Dose 1 or Dose 2 icotrokinra once daily.

The randomisation process uses an online tool.

The main study will consist of:

- Screening Period (Up to 5 weeks)
- Placebo-controlled period (Up to 16 weeks)
- Blinded active-treatment period (up to 36 weeks)
- Safety follow-up visit (4 weeks after the last dose of study treatment)

All participants who complete the main study will have the option to participate in the 52-week blinded LTE period (48 weeks of active treatment plus 4 weeks of safety follow-up).

Intervention Type

Drug

Pharmaceutical study type(s)

Pharmacodynamic, Pharmacogenomic, Therapy

Phase

Phase III

Drug/device/biological/vaccine name(s)

Icotrokinra [JNJ-77242113-AAC]

Primary outcome measure

The proportion of participants who achieve an American College of Rheumatology (ACR) ACR 20 response at week 16.

The ACR 20 responders are participants with an improvement of greater than or equal to (\geq) 20 percent (%) from baseline in both the tender and swollen joint count and in at least 3 of the 5 assessments (patient's assessment of pain visual analog scale (VAS), patient's global assessment of disease activity VAS scale, Physician's global assessment of disease activity VAS scale, Health Assessment Questionnaire and C-reactive protein).

Secondary outcome measures

1. Proportion of Participants Who Achieved Psoriatic Area and Severity Index (PASI) 75 Response at Week 16 Among Participants with Baseline Body Surface Area (BSA) Greater Than or Equal to (\geq) 3 Percent (%) and With Baseline IGA Score of ≥ 2
2. Proportion of Participants Who Achieved PASI 90 Response at Week 16 Among Participants with Baseline BSA $\geq 3\%$ and With Baseline IGA Score of ≥ 2
3. Proportion of Participants Who Achieved PASI 100 Response at Week 16 Among Participants with Baseline BSA $\geq 3\%$ and With Baseline IGA Score of ≥ 2
4. Proportion of Participants with an Investigator Global Assessment (IGA) Psoriasis Score of 0 or 1 And ≥ 2 Grade Improvement From Baseline at Week 16 Among Participants with Baseline BSA $\geq 3\%$ and With Baseline IGA Score of ≥ 2
5. Proportion of Participants who Achieved an ACR 50 Response at Week 16
6. Proportion of Participants who Achieved an ACR 70 Response at Week 16
7. Change From Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score At Week 16
8. Changes From Baseline in 36 Item Short Form Survey (SF-36) Physical Component Summary (PCS) Score at Week 16
9. Proportion of Participants With Resolution of Enthesitis at Week 16 Among Those With Enthesitis at Baseline
10. Change From Baseline in Enthesitis Score at Week 16 in Participants With Enthesitis at Baseline
11. Proportion of Participants With Resolution of Dactylitis at Week 16 Among Those With Dactylitis at Baseline
12. Change From Baseline in Dactylitis Score at Week 16 in Participants With Dactylitis at Baseline

13. Proportion of Participants who Achieved Minimal Disease Activity (MDA) at Week 16
14. Change From Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Week 16

Overall study start date

28/11/2024

Completion date

11/10/2028

Eligibility

Key inclusion criteria

1. Participants must have been previously treated with 1 biologic agent for psoriatic arthritis (PsA) or psoriasis and the reason for discontinuation must be documented.
2. Have a diagnosis of psoriatic arthritis (PsA) for at least 3 months before the first administration of study intervention and meet classification criteria for Psoriatic Arthritis (CASPAR) at screening.
3. Have active PsA as defined by:
 - 3.1. At least 3 swollen joints and at least 3 tender joints at screening and at baseline.
 - 3.2. C-reactive protein (CRP) greater than or equal to (\geq) 0.1 milligrams per deciliter (mg/dL) at screening from the central laboratory.
4. Have at least 1 of the PsA subsets: distal interphalangeal joint involvement, polyarticular arthritis with absence of rheumatoid nodules, arthritis mutilans, asymmetric peripheral arthritis, or spondylitis with peripheral arthritis.
5. Have active plaque psoriasis with at least one psoriatic plaque of \geq 2 cm diameter or nail changes consistent with psoriasis.
6. A female participant of childbearing potential must have a negative highly sensitive serum pregnancy test (Beta-hCG) at screening and a negative urine pregnancy test at Week 0 prior to administration of study intervention.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

750

Key exclusion criteria

1. Has a history or current signs or symptoms of severe, progressive, or uncontrolled renal, hepatic, cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, hematologic, rheumatologic (with the exception of PsA), psychiatric, genitourinary, or metabolic disturbances.

2. Currently has a malignancy or has a history of malignancy within 5 years prior to screening.
3. Has known allergies, hypersensitivity, or intolerance to icotrokinra or its excipients.
4. Has other inflammatory diseases that might confound the evaluations of benefit of icotrokinra therapy, including but not limited to rheumatoid arthritis (RA), systemic lupus erythematosus, or Lyme disease.
5. Participants with fibromyalgia or osteoarthritis symptoms that, in the investigator's opinion, would have the potential to interfere with efficacy assessments.

Date of first enrolment

01/03/2025

Date of final enrolment

16/09/2026

Locations

Countries of recruitment

Argentina

Australia

Brazil

Bulgaria

Canada

China

Denmark

England

Germany

Hong Kong

Hungary

India

Israel

Italy

Japan

Mexico

Poland

Romania

Spain

Taiwan

Thailand

United Kingdom

Study participating centre

Haywood Hospital

Burslem

Stoke-on-trent

United Kingdom

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Sponsor information

Organisation

Janssen-Cilag International NV

Sponsor details

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Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Janssen-Cilag International NV

Results and Publications

Publication and dissemination plan

1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Submission to regulatory authorities

Study results will be available via publication in scientific journals, the EudraCT database & presentation at scientific meetings. Results will be made available to participants via a Plain Language Summary a year after the end of the study. The summary will describe the results regardless of study outcome in language that is understandable to the general public. It will not contain individual participant results or their personal information. A copy of the Summary will be provided to the REC.

Intention to publish date

11/10/2029

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author upon reasonable request. The data sharing policy of the Janssen Pharmaceutical Companies of Johnson and Johnson is available at <https://www.janssen.com/clinical-trials/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