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A study to evaluate the efficacy and safety of Icotrokinra (JNJ-77242113) in biologic-experienced and biologic-naive participants with active psoriatic arthritis

Submission date
30/11/2024

Recruitment status
No longer recruiting

Registration date
20/01/2025

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
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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Clinical Trials Information System (CTIS)
2024-517284-23

Integrated Research Application System (IRAS)
1010955

Central Portfolio Management System (CPMS)
64272

Protocol serial number
77242113PSA3002

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 and biologic-naive 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

Primary study design
Interventional

Study design
Interventional double-blind randomized parallel group placebo-controlled trial

Study type(s)
Efficacy, Safety

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

Phase
Phase III

Drug/device/biological/vaccine name(s)
Icotrokinra [JNJ-77242113-AAC]

Primary outcome(s)
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 (>=) 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).

Key secondary outcome(s)
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 (>=) 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 >=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 >=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 >=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

Completion date
11/10/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/05/2026:
1. Have active psoriatic arthritis (PsA) despite current or previous use of greater than or equal to (>=) one of the following:

1.1. Non-biologic disease modifying antirheumatic drug (DMARD) therapy
1.2. Apremilast therapy
1.3. Biologic-agent (limited to only one)
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 three swollen joints and at least three tender joints at screening and at baseline.
3.2. C-reactive protein (CRP) greater than or equal to (>=) 0.1 milligrams per deciliter (mg/dL) at screening from the central laboratory.
4. Have at least one 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 >=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.

Previous inclusion criteria:
1. Participants must have been previously treated with one 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 three swollen joints and at least three tender joints at screening and at baseline.
3.2. C-reactive protein (CRP) greater than or equal to (>=) 0.1 milligrams per deciliter (mg/dL) at screening from the central laboratory.
4. Have at least one 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 >=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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit

100 Years

Sex
All

Total final enrolment
0

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
United Kingdom

England

Argentina

Australia

Brazil

Bulgaria

Canada

China

Denmark

Germany

Hong Kong

Hungary

India

Israel

Italy

Japan

Mexico

Poland

Romania

Spain

Taiwan

Thailand

Study participating centre
Haywood Hospital
Burslem
Stoke-on-trent
England
ST6 7AG

Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type
Industry

Funder Name
Janssen-Cilag International NV

Results and Publications

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