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

Submission date
03/02/2022

Recruitment status
No longer recruiting

Registration date
10/05/2022

Overall study status
Completed

Last Edited
04/10/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Plaque psoriasis is a common, chronic, inflammatory condition, affecting about 3.5 million patients in the United States, European Union, and Japan. Despite several advanced treatment options, a large proportion of patients are not receiving these therapies and there is a need for safer options, fewer injections, and options for more effective oral medications. The investigational drug is called JNJ-77242113. It targets immune responses in the body and skin which impact diseases, such as psoriasis.
It is hoped that targeting this process may lead to less inflammation and a reduction in psoriasis disease activity. This study is designed to see if JNJ-77242113 is better than a placebo (dummy drug) in reducing psoriasis disease activity.

Who can participate?
Patients aged 18 years and over with moderate to severe plaque psoriasis.

What does the study involve?
This study will last for a maximum of 24 weeks and is divided into three parts:
1. Screening phase: 1 visit (up to 4 weeks)
2. Treatment phase: 7 visits (16 weeks)
3. Safety follow-up phase: 1 visit (4 weeks)
During study visits a variety of tests will be carried out including, but not limited to, blood pressure, heart activity, physical exam, questionnaires and blood samples. Patients will be randomly assigned to receive either oral JNJ-77242113 at one of five different dosing regimens or placebo twice a day during the treatment phase.

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 improve symptoms of plaque psoriasis. These benefits are not guaranteed to happen and there may not be any benefit to participants by being in this study. In addition, if participants are put into treatment Group 6 (placebo) they will not receive JNJ-77242113 and will only receive placebo during this study.
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 psoriasis in the future.
Not all possible side effects and risks related to JNJ-77242113 are known and it is possible that unexpected side effects may arise or may be life-threatening. To minimise the risk associated with this, participants are frequently reviewed at every visit for side effects and adverse events. Participants are educated to report any such problems to the study staff without delay. Any serious adverse events that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team and the sponsor has implemented an Independent Data Review Committee. The participant information sheet, which will be signed by every participant agreeing to participate in the study, includes a detailed section outlining all known risks/side effects to participating in the study.

Where is the study run from?
Janssen-Cilag International NV is the sponsor for this study. The study will be run at multiple healthcare locations both within the UK and around the world.

When is the study starting and how long is it expected to run for?
January 2022 to February 2023

Who is funding the study?
Janssen Research & Development, LLC (Belgium)

Who is the main contact?
Sarah Currie (JanssenUKRegistryQueries@its.jnj.com)

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Additional identifiers

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NCT05223868

Clinical Trials Information System (CTIS)
2021-003700-41

Integrated Research Application System (IRAS)
1004415

Central Portfolio Management System (CPMS)
51021

Protocol serial number
77242113PSO2001

Study information

Scientific Title
A Phase IIb multicenter, randomized, placebo-controlled, dose-ranging study to evaluate the efficacy and safety of JNJ-77242113 for the treatment of moderate-to-severe plaque psoriasis

Acronym
FRONTIER 1

Study objectives
Main objectives:
1. To evaluate the dose-response of JNJ-77242113 at Week 16 in participants with moderate-to-severe plaque psoriasis

Secondary objectives:
2. To characterize the additional efficacy of JNJ-77242113 versus placebo in participants with moderate-to-severe plaque psoriasis
3. To evaluate the effect of JNJ-77242113 treatment on patient-reported psoriasis severity versus placebo in participants with moderate-to-severe plaque psoriasis
4. To evaluate the effect of JNJ-77242113 treatment on dermatology-specific health-related quality of life versus placebo in participants with moderate-to-severe plaque psoriasis
5. To evaluate the effect of JNJ-77242113 treatment on general health-related quality of life versus placebo in participants with moderate-to-severe plaque psoriasis
6. To assess the safety and tolerability of JNJ-77242113 in participants with moderate-to-severe plaque psoriasis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/04/2022, London-Westminster Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8066, +44 (0)207 1048236; westminster.rec@hra.nhs.uk), ref: 22/LO/0125

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

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The total duration of this study is up to 24 weeks which includes a screening period of less than or equal to (≤) 4 weeks, a 16-week treatment period, and a 4-week safety follow-up period. Participants will be randomly assigned to one of 6 treatment arms by an online interactive web randomisation system tool. Each active cohort group will also receive a placebo to maintain blinding of dose regimens throughout the trial:

Group 1 will receive dose 1 of JNJ-77242113 once daily and placebo
Group 2 will receive dose 2 of JNJ-77242113 once daily and placebo
Group 3 will receive dose 3 of JNJ-77242113 once daily and placebo
Group 4 will receive dose 1 of JNJ-77242113 twice daily and placebo
Group 5 will receive dose 3 of JNJ-77242113 twice daily and placebo
Group 6 will receive placebo twice daily

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
Percentage of participants achieving Psoriasis Area Severity Index (PASI) 75 score (greater than or equal to [≥] 75 percentage [%] improvement from baseline in PASI) determined at Week 16. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed and scored separately for erythema, induration, and scaling, which are each rated on a scale of 0 to 4 and extent of involvement on a scale of 0 to 6. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease.

Key secondary outcome(s))

1. Change from baseline in PASI Total Score reported at Week 16. Change from baseline in PASI total score will be minored from baseline to week 16 and reported at Week 16
2. Percentage of participants achieving PASI 90 score (≥90% improvement from baseline in PASI) determined at Week 16
3. Percentage of participants achieving PASI 100 score (100% improvement from baseline in PASI) determined at Week 16
4. Percentage of participants achieving an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) determined at Week 16. The IGA documents the investigator's assessment of the participant's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4)
5. Percentage of participants achieving an Investigator's Global Assessment (IGA) Score of Cleared (0) determined at Week 16
6. Change from baseline in Body Surface Area (BSA) reported at Week 16. Body Surface Area is a commonly used measure of severity of skin disease. It is defined as the percentage of the surface area of the body involved with the condition being assessed, (that is, plaque psoriasis)
7. Change from baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Scores reported at Week 16. The PSSD includes a patient-reported outcome (PRO) questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two subscores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
8. Change from baseline in PSSD Signs Score reported at Week 16
9. Percentage of participants achieving PSSD Symptoms Score = 0 determined at Week 16 in participants with a baseline Symptoms Score ≥1
10. Percentage of participants achieving PSSD Sign Score = 0 determined at Week 16 in participants with a baseline Sign Score ≥1
11. Percentage of participants achieving a Dermatology Life Quality Index (DLQI) of 0 or 1 determined at Week 16 in participants with baseline DLQI Score >1. The DLQI is a dermatology-specific health-related quality of life (HRQoL) instrument designed to assess the impact of the disease on a participant's HRQoL. It is a 10-item questionnaire that assesses HRQoL over the past 7 days and in addition to evaluating overall HRQoL, can be used to assess 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. The total score ranges from 0 to 30 with a higher score indicating a greater impact on HRQoL.
12. Change from baseline in Patient-reported Outcomes Measurement Information System (PROMIS-29) Domain Score reported at Week 16. The PROMIS-29 is a 29-item generic HRQoL instrument assessing 7 PROMIS domains (depression, anxiety, physical function, pain interference, fatigue, sleep disturbance, and ability to participate in social roles and activities) with 4 questions for each domain. These questions are ranked on a 5-point Likert scale. There is also a numerical rating scale that ranges from 0 (No pain) to 10 (Worst pain imaginable) for pain intensity. The raw domain scores are converted to standardized T-scores with a mean of 50 and a standard deviation of 10. Higher scores on anxiety, depression, fatigue, sleep disturbance, and pain interference indicate more severe symptoms. Higher scores on physical function and social participation indicate better health outcomes.
13. Percentage of participants achieving ≥5-point improvement from baseline in PROMIS-29 Domain Score determined at Week 16

14. Number of participants with Adverse Events (AEs) monitored up to Week 24. An adverse event (AE) is any untoward medical event that occurs in a participant administered an investigational product, and it does not necessarily indicate only events with a clear causal relationship with the relevant investigational product
15. Number of participants with Serious Adverse Events (SAEs) monitored up to Week 24. SAE is an adverse event resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission of any infectious agent via a medicinal product or medically important.

Completion date
24/02/2023

Eligibility

Key inclusion criteria
1. Participant has a diagnosis of plaque psoriasis, with or without psoriatic arthritis (PsA), for at least 6 months prior to the first administration of study intervention
2. Participant is a candidate for phototherapy or systemic treatment for plaque psoriasis
3. Participant has a total body surface area (BSA) greater than or equal to (≥) 10 percent (%) at screening and baseline
4. Participant has a total Psoriasis area and severity index (PASI) ≥12 at screening and baseline
5. Participant has a total Investigator global assessment (IGA) ≥3 at screening and baseline

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participant has a nonplaque form of psoriasis (for example, erythrodermic, guttate, or pustular)
2. Participant has 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. Participant have previously received any other therapeutic agent directly targeted to interleukin 23 receptor (IL-23R) (including but not limited to guselkumab, tildrakizumab, or risankizumab)
4. Participant has received any therapeutic agent directly targeted to interleukin 17 receptor (IL-17) or interleukin 12/23 receptor (IL-12/23) (including but not limited to secukinumab, ixekizumab, brodalumab, or ustekinumab) or has received anti-tumor necrosis factor [TNF]-alpha biologic therapy (including, but not limited to adalimumab) within 12 weeks or 5 half-lives,

whichever is longer, of the first administration of study intervention
5. Participant has received agents that deplete B cells (including, but not limited to, rituximab, or alemtuzumab) within 26 weeks of the first administration of study intervention

Date of first enrolment
24/01/2022

Date of final enrolment
17/10/2022

Locations

Countries of recruitment
United Kingdom

England

Canada

Czech Republic

France

Germany

Japan

Korea, South

Poland

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Taiwan

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Study participating centre
Dermatology Associates
1730 Minor Avenue
Seattle
United States of America
98101

Study participating centre
Medical Dermatology Specialists
1331 N. 7th Street
Phoenix
United States of America
85006

Study participating centre
Premier Clinical Research
324 South Sherman
Spokane
United States of America
99202

Study participating centre
Olympian Clinical Research
1201 S Myrtle Ave
Clearwater
United States of America
33756

Study participating centre
Oakview Dermatology
2111 East State Street
Athens
United States of America
45701

Sponsor information

Organisation
Janssen (Belgium)

ROR
https://ror.org/04yzcpd71

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other unpublished results			04/10/2024	No	No