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A study comparing JNJ-77242113 and ustekinumab in adult participants with moderate to severe plaque psoriasis

Submission date
08/02/2025

Recruitment status
Recruiting

Registration date
26/03/2025

Overall study status
Ongoing

Last Edited
04/06/2025

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
Plaque psoriasis is a skin disease that causes red, scaly, and sometimes painful and itchy patches on the skin. Targeting interleukin-23 (IL-23) (a specific type of protein involved in inflammation) to prevent it from binding to its receptor (the specific protein it binds to) is a highly validated approach for treating moderate to severe psoriasis. The study drug, JNJ-77242113, is a medicine that blocks the IL-23 receptor by binding to it. By blocking the effects of IL-23, inflammation is reduced, thus preventing disease from getting worse. The purpose of this study is to check how well JNJ-77242113 works compared to placebo (does not contain any active medication) in participants with moderate to severe plaque psoriasis.

Who can participate?
Participants aged 12 years old and over with moderate to severe plaque psoriasis.

What does the study involve?
Participants enrolled on 2 cohorts:
Cohort A: Never received systemic therapy or have received systemic therapy but have discontinued for reasons other than those mentioned in Cohort B.
Cohort B: Received systemic therapy but responded poorly, have not tolerated or have been advised not to take.
Study includes:
Screening Period (Up to 5 Weeks)
Treatment Period: Participants to be randomly assigned into arms:
JNJ-77242113:
• JNJ-77242113 from Week 0 to Week 104
• Matching placebo for ustekinumab at Weeks 0,4 and 16
Placebo:
• Matching placebo for JNJ-77242113 from Week 0 to Week 16
• Matching placebo for ustekinumab at Weeks 0, 4 and 16
• JNJ-77242113 from Week 16 to Week 104
Ustekinumab:

• Ustekinumab at Weeks 0, 4 and 16
• Matching placebo for JNJ-77242113 from Week 0 to Week 28
• JNJ-77242113 from Week 28 to Week 104.
Safety follow-up Period: Up to 4 weeks after treatment completion/discontinuation
Safety assessments include monitoring of adverse events, laboratory tests, electrocardiograms, physical examinations, vital signs, and patient-reported health questionnaires. All side effects will be recorded till the study ends (up to approximately Week 113).

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 plaque psoriasis. However, this cannot be guaranteed because JNJ-77242113 is still under investigation as a treatment, and it is not known whether JNJ-77242113 will work.
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 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. The possible side effects for JNJ-77242113 include hypersensitivity reactions (exaggerated response from immune system), antidrug antibody (ADA) production (antibodies developed against drugs reducing their therapeutic efficacy), and infections. The possible side effects for ustekinumab include hypersensitivity, infections, malignancies, cardiovascular events, and advice to avoid the use of live vaccines and exercise caution with concomitant immunosuppressants during treatment. There are other, less frequent risks associated with ustekinumab. 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 and risks related to JNJ-77242113 are known at this moment. During the study, the sponsor may learn new information about JNJ-77242113. 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 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?
Janssen-Cilag International N.V.

When is the study starting and how long is it expected to run for?
February 2025 to December 2027

Who is funding the study?
Janssen Research and Development

Who is the main contact?
Medical Information and Product Information Enquiry, medinfo@its.jnj.com

Contact information

Type(s)
Scientific

Contact name
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Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
2024-515706-77

IRAS number
1011110

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
7724213PSO3006, CPMS 64768

Study information

Scientific Title

A phase III multicenter, randomized, double-blind, placebo-controlled and ustekinumab active comparator-controlled study to evaluate the efficacy and safety of JNJ-77242113 for the treatment of participants with moderate to severe plaque psoriasis

Acronym
Iconic Ascend

Study objectives
To evaluate the efficacy of JNJ-77242113 compared with placebo in participants with moderate to severe plaque psoriasis.

The key secondary objectives of the trials are:
To further evaluate the efficacy of JNJ-77242113 compared with placebo in participants with moderate to severe plaque psoriasis.
To evaluate the efficacy of JNJ-77242113 compared with ustekinumab in participants with moderate to severe plaque psoriasis.
To evaluate the effect of JNJ-77242113 treatment on patient-reported psoriasis symptom and itch severity compared with placebo in participants with moderate to severe psoriasis.
Due to character limitation to see a full list of secondary objectives, please see the protocol.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/03/2025, Tyne and Wear South Rec (NHSBT, Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)2071048120; tyneandwearsouth.rec@hra.nhs.uk), ref: 25/NE/0041

Study design
Randomized placebo- and active-controlled double-blind parallel-group study

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Plaque psoriasis

Interventions
Experimental: Arm 1: JNJ 77242113
Participants will receive JNJ-77242113 once daily from Week 0 through Week 104. All participant will receive ustekinumab matching placebo at Week 0, 4 and 16 to maintain the blind.
Drug: JNJ-77242113 will be administered orally.
Drug: Matching Placebo to Ustekinumab
Matching placebo will be administered subcutaneously.

Placebo Comparator: Arm 2: Placebo
Participants will receive matching placebo for JNJ-77242113 from Week 0 through Week 16, matching placebo for ustekinumab at Week 0, 4 and 16 and JNJ-77242113 from Week 16 through Week 104.
Drug: JNJ-77242113 will be administered orally.
Drug: Matching Placebo to JNJ-77242113
Matching placebo will be administered orally.
Drug: Matching Placebo to Ustekinumab
Matching placebo will be administered subcutaneously.

Active Comparator: Arm 3: Ustekinumab
Participants will receive Ustekinumab at Week 0, Week 4, and Week 16 followed by JNJ-77242113 once daily from Week 28 through Week 104. Participants will receive both Ustekinumab and placebo for JNJ-77242113 to maintain the blind through Week 28.
Drug: JNJ-77242113 will be administered orally.
Drug: Matching Placebo to JNJ-77242113
Matching placebo will be administered orally.
Drug: Ustekinumab
Ustekinumab will be administered subcutaneously.
Other Names:
• STELARA
• CNTO 1275

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic, Pharmacogenomic, Therapy, Others (Biomarkers)

Phase
Phase III

Drug/device/biological/vaccine name(s)
JNJ-77242113 [JNJ-77242113-AAC] , Stelara 90mg solution for injection in pre-filled syringe [Ustekinumab]

Primary outcome measure
1. JNJ-77242113 and Placebo Group: Percentage of Participants with Investigator's Global Assessment (IGA) Score of 0 or 1 and Greater than or Equal to (>=) 2 Grade Improvement from Baseline at Week 16 IGA score is given based on the investigator’s assessment of the participant’ s plaque psoriasis at a given time point.
Overall lesions are graded for induration, erythema, and scaling. The participant’s plaque psoriasis is assessed as: cleared (0), minimal (1), mild (2), moderate (3), or severe (4).

2. JNJ-77242113 and Placebo Group: Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI) 90 Response at Week 16 PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In this 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 (none) to 4 (severe) and extent of involvement on a scale of 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents participants achieving at least a 90 percent improvement from baseline in the PASI score.

Secondary outcome measures

1. JNJ-77242113 and Placebo Group: Percentage of Participants Achieving PASI 75 Response at Week 16 PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In this 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 (none) to 4 (severe) and extent of involvement on a scale of 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 75 response represents participants achieving at least a 75 percent improvement from baseline in the PASI score.
2. JNJ-77242113 and Placebo Group: Percentage of Participants Achieving PASI 100 Response at Week 16 PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In this 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 (none) to 4 (severe) and extent of involvement on a scale of 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 100 response represents participants achieving at least a 100 percent improvement from baseline in the PASI score.
3. JNJ-77242113 and Placebo Group: Percentage of Participants with IGA Score of 0 at Week 16 4. IGA score is given based on the investigator’s assessment of the participant’s plaque psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant’s plaque psoriasis is assessed as: cleared (0), minimal (1), mild (2), moderate (3), or severe (4).
5. JNJ-77242113 and Ustekinumab Group: Percentage of Participants with IGA Score of 0 at Week 28 IGA score is given based on the investigator’s assessment of the participant’s plaque psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant’s plaque psoriasis is assessed as: cleared (0), minimal (1), mild (2), moderate (3), or severe (4).
6. JNJ-77242113 and Ustekinumab Group: Percentage of Participants Achieving PASI 90 Response at Week 28 PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In this 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 (none) to 4 (severe) and extent of involvement on a scale of 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents participants achieving at least a 90 percent improvement from baseline in the PASI score.
7. JNJ-77242113 and Ustekinumab Group: Percentage of Participants Achieving PASI 100 Response at Week 28 PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In this 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 (none) to 4 (severe) and extent of involvement on a scale of 0 (indicates no involvement) to 6 (90% to 100% 8. involvement). The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 100 response represents participants achieving at least a 100 percent improvement from baseline in the PASI score.
9. JNJ-77242113 and Placebo Group: Percentage of Participants with PSSD Symptom Score of 0 at Week 16 PSSD includes patient-reported outcome (PRO) questionnaires designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. This PRO includes 11 items in total, with 5 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and 6 items covering participant observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding). The PSSD itch score will range from 0 to 10. Two sub scores 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.
10. JNJ-77242113 and Placebo Group: Percentage of Participants with >= 4 Point Improvement from Baseline in PSSD Itch Score at Week 16 PSSD includes PRO questionnaires designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. This PRO includes 11 items in total, with 5 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and 6 items covering participant observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding). The PSSD itch score will range from 0 to 10. Two sub scores 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.
11. Number of Participants Reporting Adverse Events (AEs) and Serious Adverse Events (SAEs) up to Week 108. An AE is any untoward medical occurrence in a clinical study participant administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. SAE is any untoward medical occurrence that results in: death, is life-threatening, requires in-patient hospitalization/prolongs existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of infectious agent via medicinal product & is medically important.
12. JNJ-77242113 and Placebo Group: Percentage of Participants with PSSD Sign Score of 0 at Week 16 PSSD includes PRO questionnaires designed to measure the severity of psoriasis symptoms and signs for the assessment of treatment benefit. This PRO includes 11 items in total, with 6 items covering participant observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding). A 0 to 10 numerical rating scale for severity is used to rank the psoriasis sign score. A higher score indicates more severe disease.
13. JNJ-77242113 and Placebo Group: Change from Baseline in Dermatology Life Quality Index (DLQI) Score at Week 16. DLQI will be utilized in the adult population and is a dermatology specific health related quality of life (HRQoL) instrument designed to assess the impact of the disease on the HRQoL It is a 10-item questionnaire that 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 greater impact on HRQoL.
14. JNJ-77242113 and Placebo Group: Percentage of Participants with DLQI Score of 0 or 1 at Week 16 DLQI will be utilized in the adult population and is a dermatology specific HRQoL instrument designed to assess the impact of the disease on the HRQoL It is a 10 item questionnaire that 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 greater impact on HRQoL.
15. JNJ-77242113 and Placebo Group: Change from Baseline in Body Surface Area (BSA) Score at Week 16 BSA is a commonly used measure of involvement of skin disease. It is defined as the

percentage of surface area of the body involved with the condition being assessed, (that is., plaque psoriasis). The handprint method for assessing BSA will be used, where the surface area of the participant's hand including the palm and all 5 digits is used as a guide to estimate 1% BSA.
16. JNJ-77242113 and Ustekinumab Group: Percentage of Participants with >= 4 Point Improvement from Baseline in PSSD Itch Score at Week 28 PSSD includes PRO questionnaires designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. This PRO includes 11 items in total, with 5 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and 6 items covering participant observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding). The PSSD itch score will range from 0 to 10. Two sub scores 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.
17. JNJ-77242113 and Ustekinumab Group: Change from Baseline in PSSD Sign Score at Week 28 PSSD includes PRO questionnaires designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. This PRO includes 11 items in total, with 5 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and 6 items covering participant observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding). The PSSD itch score will range from 0 to 10. Two sub scores 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.
18. JNJ-77242113 and Ustekinumab Group: Change from Baseline in PSSD Symptom Score at Week 28 PSSD includes PRO questionnaires designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. This PRO includes 11 items in total, with 5 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and 6 items covering participant observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding). The PSSD itch score will range from 0 to 10. Two sub scores 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.
19. JNJ-77242113 and Ustekinumab Group: Percentage of Participants with PSSD Sign Score of 0 at Week 28 PSSD includes PRO questionnaires designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. This PRO includes 11 items in total, with 5 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and 6 items covering participant observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding). The PSSD itch score will range from 0 to 10. Two sub scores 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.
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21. JNJ-77242113 and Ustekinumab Group: Change from Baseline in DLQI Score at Week 28 DLQI will be utilized in the adult population and is a dermatology specific HRQoL instrument designed to assess the impact of the disease on the HRQoL It is a 10-item questionnaire that 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 greater impact on HRQoL.
22. JNJ-77242113 and Ustekinumab Group: Percentage of Participants with DLQI Score of 0 or 1 at Week 28 DLQI will be utilized in the adult population and is a dermatology specific HRQoL

instrument designed to assess the impact of the disease on the HRQoL. It is a 10-item questionnaire that 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 greater impact on HRQoL.
23. JNJ-77242113 and Ustekinumab Group: Change from Baseline in BSA Score at Week 16 BSA is a commonly used measure of involvement of skin disease. It is defined as the percentage of surface area of the body involved with the condition being assessed, (ie, plaque psoriasis). The handprint method for assessing BSA will be used, where the surface area of the participant's hand including the palm and all 5 digits is used as a guide to estimate 1% BSA.
24. JNJ-77242113 and Ustekinumab Group: Percentage of Participants with IGA Score of 0 at Week 16 IGA score is given based on the investigator’s assessment of the participant’s plaque psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant’s plaque psoriasis is assessed as: cleared (0), minimal (1), mild (2), moderate (3), or severe (4).
25. JNJ-77242113 and Ustekinumab Group: Percentage of Participants Achieving PASI 90 Response at Week 16 PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In this 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 (none) to 4 (severe) and extent of involvement on a scale of 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents participants achieving at least a 90 percent improvement from baseline in the PASI score.
26. JNJ-77242113 and Ustekinumab Group: Percentage of Participants Achieving PASI 100 Response at Week 16 PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In this 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 (none) to 4 (severe) and extent of involvement on a scale of 0 (indicates no involvement) to 6 (90% to 100% involvement). The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 100 response represents participants achieving at least a 100 percent improvement from baseline in the PASI score.

Overall study start date
05/02/2025

Completion date
29/12/2027

Eligibility

Key inclusion criteria
1. Aged 12 years of age or older at the screening visit. Note for the UK we will only be accepting participants aged 18 and older and will not be including adolescents in the trial
2. Diagnosis of moderate to severe plaque psoriasis, with or without PsA, for at least 26 weeks before 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 moderate to severe plaque psoriasis

Participant type(s)
Patient

Age group
Mixed

Lower age limit
12 Years

Sex
Both

Target number of participants
675

Key exclusion criteria
1. Nonplaque form of psoriasis (for example [e.g.], erythrodermic, guttate, or pustular)
2. Current drug-induced psoriasis (e.g., 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-77242113, ustekinumab, or its excipients
4. Major surgical procedure within 8 weeks before screening, or will not have fully recovered from surgical procedure, or has a surgical procedure planned during the time the participant is expected to participate in the study
5. Transplanted organ (with exception of a corneal transplant greater than [>] 12 weeks before the first administration of study intervention)

Date of first enrolment
15/04/2025

Date of final enrolment
05/11/2025

Locations

Countries of recruitment
Argentina

Australia

Belgium

Canada

Denmark

England

Germany

Hungary

Poland

Portugal

Spain

United Kingdom

United States of America

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Russells Hall Hospital
Pensnett Road
Dudley
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DY1 2HQ

Study participating centre
Queen Elizabeth Hospital Kings Lynn
Gayton Road
Queen Elizabeth Hospital Site
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PE30 4ET

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
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M6 8HD

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Guys and St Thomas NHS Foundation Trust
Great Maze Pond
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United Kingdom
SE1 9RT

Study participating centre
Royal Berkshire Hospital
Craven Road,
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Reading
United Kingdom
RG1 5AN

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
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HA1 3UJ

Study participating centre
Russells Hall Hospital
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Sponsor information

Organisation
Janssen-Cilag International NV

Sponsor details
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2333 CM
-
ClinicalTrialsEU@its.jnj.com

Sponsor type
Industry

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

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Internal report

3. Conference presentation
The study's results will be available to the wider scientific community through publication in scientific journals and presentation at scientific meetings. At the end of the study, a plain-language summary will be provided to participants. In addition, the results will be published in the EudraCT database in accordance with HRA requirements (a lay summary of the results will be included in the final HRA Report).

Intention to publish date
29/12/2028

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 https://yoda.yale.edu/

IPD sharing plan summary
Available on request