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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)

Contact information

Type(s)
Principal Investigator

Contact name
Dr Andrew Pink

ORCID ID
http://orcid.org/0000-0001-5151-5539

Contact details
Guy’s Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Type(s)
Scientific

Contact name
Dr Medical Information and Product Information Enquiry

Contact details
50-100 Holmers Farm Way
High Wycombe

United Kingdom
HP12 4DP
+44 (0)800 731 8450 / 10494 567 444
medinfo@its.jnj.com

Additional identifiers

EudraCT/CTIS number
2021-003700-41

IRAS number
1004415

ClinicalTrials.gov number
NCT05223868

Secondary identifying numbers
77242113PSO2001, IRAS 1004415, CPMS 51021

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure

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.

Secondary outcome measures

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.

Overall study start date
21/01/2022

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

Age group
Adult

Sex
Both

Target number of participants
240

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
Canada

Czech Republic

England

France

Germany

Japan

Korea, South

Poland

Spain

Taiwan

United Kingdom

United States of America

Study participating centre

Castle Hill Hospital
Cottingham
United Kingdom
HU16 5JQ

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

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

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

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

Study participating centre
Innovaderm Research
3530 Boulevard Saint-Laurent
Montreal
Canada
H2X 2V1

Study participating centre
Skin Centre For Dermatology
775 Monaghan Road
Peterborough
Canada
K9J 5K2

Study participating centre
Dr. Chih-Ho Hong Medical
15300 105 Avenue
Surrey
Canada
V3R 6A7

Study participating centre
Dermedge Research
333 Lakeshore Road West
Mississauga
Canada
L4Y 4C5

Study participating centre
K. Papp Clinical Research
135 Union Street East
Waterloo
Canada
N2J 1C4

Study participating centre
Dermatology Research Institute Inc.
8500 Blackfoot Trail SE
Calgary
Canada
T2J 7E1

Study participating centre
Xlr8 Medical Research
2425 Tecumseh Road East

Windsor
Canada
N8W 1E6

Study participating centre
Dermatrials Research
25 Charlton Avenue East
Hamilton
Canada
L8N 1Y2

Study participating centre
Fakultni Nemocnice Kralovske Vinohrady
Srobarova 50
Praha
Czech Republic
775 20

Study participating centre
Fn Plzen Dermatovenerologicka Klinika (Main)
Edvarda Benese 13
Plzen
Czech Republic
305 99

Study participating centre
Ccbr Klinicka Centra Czech, A.S.
Trida Miru 2800
Pardubice
Czech Republic
53002

Study participating centre
Nemocnice Ceske Budejovice, A.S.
Bozeny Nemcove 54
Ceske Budejovice
Czech Republic
37087

Study participating centre
Vseobecna Fakultní Nemocnice
U Nemocnice 2
Praha 2
Czech Republic
128 08

Study participating centre
Dermamedica S.R.O.
Komenského 420
Nachod
Czech Republic
547 01

Study participating centre
Clintrial S.R.O.
Pocernicka 1427/16
Praha
Czech Republic
10 100 00

Study participating centre
Nemocnice Na Bulovce
Budínova 67/2
Praha 8
Czech Republic
180 81

Study participating centre
Praglandia, S.R.O.
Ostrovskeho 253/3
Prague
Czech Republic
15000

Study participating centre
Dermatologie Prof. Hercogove
Chlumcanskeho 497/5
Prague
Czech Republic
180 81

Study participating centre
Ccr Prague S.R.O.
Vinohradska 1597/174
Praha
Czech Republic
130 00

Study participating centre
Hia Sainte Anne
2 boulevard Sainte Anne
Toulon
France
83800

Study participating centre
Hopital Charles Nicolle
1 rue de Germont
Rouen
France
76031

Study participating centre
Hôpital Edouard Herriot
5 Pl D Arsonval
Lyon Cedex 03
France
69437

Study participating centre
Centre Hospitalier Le Mans
194 Avenue Rubillard
Le Mans
France
72037

Study participating centre
Chu Saint-Etienne
Avenue Albert Raimond

St Priest En Jarez
France
42270

Study participating centre
Polyclinique De Courlancy
38bis Rue de Courlancy
Reims
France
51100

Study participating centre
Chu De Grenoble - Hôpital Albert Michallon
Boulevard de la Chantourne
La Tronche
France
38700

Study participating centre
Ich Hopital A. Morvan
2 Avenue Marechal Foch
Brest
France
29200

Study participating centre
Universitatsklinikum Carl Gustav Carcus Dresden
Fetscherstr. 74
Dresden
Germany
01307

Study participating centre
Mensingderma Research Gmbh
Heegbarg 4
Hamburg
Germany
22391

Study participating centre
Universitatsklinikum Schleswig-Holstein - Kiel
Arnold-Heller-Str. 3, Haus 19
Kiel
Germany
24105

Study participating centre
Praxis Für Dermatologie Und Venerologie
Hauptstrasse 36a
Dresden
Germany
01097

Study participating centre
Rothhaar Studien Gmbh
Dermatologisches Studienzentrum
Berlin
Germany
10783

Study participating centre
Hautarztpraxis
Annenstraße 151
Witten
Germany
58453

Study participating centre
Charite - Universitatsmedizin Berlin (Ccm)
Charitéplatz 1
Berlin
Germany
10117

Study participating centre
Uniklinik Münster -Klinik U. Pol. F. Hautkrankheiten
Von-Esmarch-Straße 58
Munster
Germany
48149

Study participating centre
Niesmann & Othlinghaus Gbr
Alleestraße 80
Bochum
Germany
44793

Study participating centre
Universitatsklinikum Frankfurt
Theodor-Stern-Kai 7
Frankfurt am Main
Germany
60590

Study participating centre
Universitätsklinikum Heidelberg
Im Neuenheimer Feld 440
Heidelberg
Germany
69120

Study participating centre
Dermatologische Gemeinschaftspraxis
Am Bahnhof 1
Mahlow
Germany
15831

Study participating centre
Universitätsklinikum Leipzig Aör
Klinik f. Dermatologie
Leipzig
Germany
04103

Study participating centre
Isa - Interdisciplinary Study Association Gmbh
Rankestrasse 34

Berlin
Germany
10789

Study participating centre
Universitätsmedizin Der Johannes Gutenberg-Universität Mainz
Langenbeckstrasse 1
Mainz
Germany
55131

Study participating centre
Fachklinik Bad Bentheim
Am Bade 1
Bad Bentheim
Germany
48455

Study participating centre
Rosenpark Research Gmbh
Rheinstrasse 1
Darmstadt
Germany
64283

Study participating centre
Universitatsklinikum Bonn
Klinik und Poliklinik für Dermatologie und Allergologie
Bonn
Germany
53127

Study participating centre
Universitaetsklinikum Koeln
Kerpener Str. 62
Koeln
Germany
50937

Study participating centre
Derma-Study-Center Friedrichshafen Gmbh
Charlottenstrasse 12/1
Friedrichshafen
Germany
88045

Study participating centre
Seibo International Catholic Hospital
2-5-1 Nakaochiai, Shinjuku-ku
Tokyo
Japan
161-8521

Study participating centre
Kume Clinic
1-65-2, Otorihigashimachi, Nishi Ku
Osaka Fu
Japan
593-8324

Study participating centre
Miyata Dermatology Clinic
1147 Matsudo
Matsudo
Japan
271-0092

Study participating centre
Sapporo Skin Clinic
2-1-1 Minami-3Jo Nishi
Sapporo
Japan
060-0063

Study participating centre
Takagi Clinic
Nishi-sanjo Minami 4-16
Obihiro-shi
Japan
080-0013

Study participating centre
Yamanashi Prefectural Central Hospital
1-1-1 Fujimi, Kofu-City, Yamanashi
Kofu
Japan
400-8506

Study participating centre
Nomura Dermatology Clinic
4-27-14 tanmachi
Yokohama
Japan
221-0825

Study participating centre
Meiwa Hospital
4-31, Agenaruo cho
Nishinomiya
Japan
663-8186

Study participating centre
Charme Clinique
68-5, Akiyama
Matsudo-shi
Japan
270-2223

Study participating centre
Shizuoka Prefectural General Hospital
4-27-1, Kitaando, Aoi-ku
Shizuoka
Japan
420-8527

Study participating centre
Kumamoto Kenhoku Hospital
550, Tamana

Tamana
Japan
865-0005

Study participating centre
Shirasaki Dermatology Clinic
3-5-33 Ekinan
Takaoka
Japan
933-0871

Study participating centre
Toyama Prefectural Central Hospital
2-2-78 Nishinagae Toyama-shi
Toyama
Japan
930-8550

Study participating centre
Mita Dermatology Clinic
4-5-8,Shiba
Minato
Japan
108-0014

Study participating centre
Seoul National University Bundang Hospital
82, Gumi-ro,173 Beon-gil
Seongnam
Korea, South
463-707

Study participating centre
Konkuk University Medical Center
120-1 NeunGdong-ro, Gwangjin-Gu
Seoul
Korea, South
05030

Study participating centre
Pusan National University Hospital
179 Gudeok-Ro
Busan
Korea, South
49241

Study participating centre
Kyunghee University Hospital
23 Kyungheedae-Ro
Seoul
Korea, South
102-1703

Study participating centre
Asan Medical Center
88, Olympic-ro 43-gil, Songpa-gu,
Seoul
Korea, South
05505

Study participating centre
Seoul National University Hospital
101, Daehak-ro
Seoul
Korea, South
03080

Study participating centre
Severance Hospital, Yonsei University Health System
50-1, Yonsei-ro, Seodaemun-gu
Seoul
Korea, South
03722

Study participating centre
Wromedica
Mickiewicza 91
Wroclaw
Poland
51-685

Study participating centre
Dermodent Centrum Medyczne Aldona Czajkowska Rafał Czajkowski S.C.
Tuberozy 3
Osielsko
Poland
86031

Study participating centre
Nzoz Zdrowie Osteo-Medic
ul. Wiejska 81,
Bialystok
Poland
15-351

Study participating centre
Dermed Centrum Medyczne Sp. Z O.O
ul. Piotrkowska 48
Lodz
Poland
90-265

Study participating centre
Royalderm Agnieszka Nawrocka
K.Kieślowskiego 3B/3
Warszawa
Poland
02962

Study participating centre
Klinika Ambroziak Estederm Sp. Z O.O
Kosiarzy 9A
Warsaw
Poland
02-953

Study participating centre
Nzoz Specderm
Kardynala Stefana Wyszynskiego 10 lokal 11

Bialystok
Poland
15-888

Study participating centre
Diamond Clinic Specjalistyczne Poradnie Lekarskie
Stefana Rogozinskiego 6/U3
Krakow
Poland
31-559

Study participating centre
Hosp. Univ. I Politecni La Fe
Avda. Fernando Abril Martorell 106, Torre C, Planta 7
Valencia
Spain
46026

Study participating centre
Hosp. Univ. 12 De Octubre
Avda. Cordoba sn
Madrid
Spain
28041

Study participating centre
Hosp. Univ. Germans Trias I Pujol
Ctra. De Canyet s/n
Barcelona
Spain
08916

Study participating centre
Hosp. De Manises
Av. De la Generalitat Valenciana 50
Valencia
Spain
46940

Study participating centre
Hosp. Provincial De Pontevedra
C/ Simón Bolivar s/n
Pontevedra
Spain
36001

Study participating centre
Hosp. Univ. De Cruces
Plaza de Cruces, S/N
Barakaldo
Spain
48902

Study participating centre
Hosp. Reina Sofia
C/ Menéndez Pidal s/n
Córdoba
Spain
14004

Study participating centre
Hosp. Univ. De Basurto
Avenida de Montevideo, 18
Bilbao
Spain
48013

Study participating centre
National Taiwan University Hospital
Dermatology Department
Taipei City
Taiwan
10048

Study participating centre
Chang-Gung Memorial Hospital, Linkou Branch
No.5 Fuxing street
Taoyuan
Taiwan
333

Study participating centre
National Cheng Kung University Hospital
138 Sheng-Li Road
Tainan
Taiwan
70403

Study participating centre
Chang Gung Memorial Hospital
Kaohsiung Branch
Kaohsiung
Taiwan
83342

Study participating centre
Windsor Dermatology, Pc
59 One Mile Rd Ext Ste G
East Windsor
United States of America
08520

Study participating centre
Oregon Medical Research Center
9495 SW Locust Street
Portland
United States of America
97223

Study participating centre
Arlington Dermatology
5301 Keystone Ct.
Rolling Meadows
United States of America
60008

Study participating centre
Modern Research Associates
9101 N. Central Expressway

Dallas
United States of America
75231

Study participating centre
Renstar Medical Research
21 NE 1st Ave
Ocala
United States of America
34470

Study participating centre
Dawes Fretzin Clinical Research Group, Llc
7910 N Shadeland Ave
Indianapolis
United States of America
46250

Study participating centre
University Of Pittsburgh
Department Of Dermatology
3601 5th Ave
Pittsburgh
United States of America
15213

Study participating centre
Forcare Clinical Research, Inc.
15416 North Florida Avenue
Tampa
United States of America
33613

Study participating centre
Clinical Partners
1524 Atwood Avenue
Johnston
United States of America
02919

Study participating centre
Indiana Clinical Trial Center
824 Edwards Drive
Plainfield
United States of America
46168

Study participating centre
Alliance Dermatology And Mohs Center, P.C.
4045 E Bell Rd
Phoenix
United States of America
85032

Study participating centre
Austin Institute For Clinical Research
1601 E Pflugerville Pkwy
Pflugerville
United States of America
78660

Study participating centre
Dermassociates, Pc
15245 Shady Grove Road
Rockville
United States of America
20850

Study participating centre
Virginia Clinical Research
6160 Kempville Road
Norfolk
United States of America
23502

Study participating centre
Oregon Dermatology And Research Center
2565 NW Lovejoy

Portland
United States of America
97210

Study participating centre
Center For Clinical Studies
1401 Binz Street
Houston
United States of America
77004

Study participating centre
University Of Utah
243 East 6100 South
Murray
United States of America
84107

Study participating centre
The South Bend Clinic Center For Research
211 N Eddy St
South Bend
United States of America
46617-2808

Study participating centre
Alpha Dermatology Of Pa, Llc
670 Lawn Ave
Sellersville
United States of America
18960

Study participating centre
Ccd Research, Pllc
1 Willowbrook Road
Cromwell
United States of America
06416

Study participating centre
Center For Clinical Studies
451 North Texas Avenue
Webster
United States of America
77598

Study participating centre
Hamzavi Dermatology
2950 Keewahdin Road
Fort Gratiot
United States of America
48059

Study participating centre
Vivida Dermatology
2110 East Flamingo Road, Suite 213
Las Vegas
United States of America
89119

Study participating centre
Pacific Skin Institute
1495 River Park Drive
Sacramento
United States of America
95815

Study participating centre
Synergy Clinical Research
595 Buckingham Way
San Francisco
United States of America
94132

Study participating centre
Atlanta Dermatology, Vein & Research Center
11800 Atlantis Place
Alpharetta
United States of America
30022

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)

Sponsor details
Turnhoutseweg 30
Beerse
Belgium
2340
-
prderacta@prdgb.jnj.com

Sponsor type
Industry

Website
https://www.janssen.com/netherlands/

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

Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Study results will be available to participants via the provision of a Plain Language Summary at the end of the study and in addition results will be published in the EudraCT database

Intention to publish date
31/10/2024

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