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An experimental study to assess a diphenylcyclopropenone skin challenge model in healthy participants for the evaluation of immunomodulatory therapies

Submission date 04/12/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/12/2025	**Overall study status** Ongoing	
Last Edited 08/12/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Developing new treatments for conditions like autoimmune diseases and cancer is time-consuming, costly, and often unsuccessful. As it is difficult to test drug effects in healthy people, early studies usually take place in diseased participants, which adds risks.
In this study, researchers will use a skin challenge model with DPCP (a chemical that causes mild skin reaction) initially by exposing the skin to it and then re-applying it. Researchers can study the immune system's response by evaluating skin reactions after DPCP exposure.
Researchers want to assess how the immune system reacts to DPCP (given alone or along with approved available drugs) in healthy participants when their skin is exposed to it several times.

Who can participate?
Healthy participants aged between 18 to 55 years

What does the study involve?
The study consists of:
1. Screening period (Up to 28 days)
2. Sensitization and individual dose-selection period (Day 1 to Day 31):
Sensitization: DPCP will be applied on skin and removed after some time.
Individual dose-selection: Increasing dose levels of DPCP will be applied and skin will be assessed at different time points. Lowest dose that causes a mild or clearly visible skin reaction will be selected.
3. Rechallenge 1 (Approximately Day 50 to Day 57) and Randomization: DPCP will be given at selected individual dose, and skin will be assessed at different time points.
Participants will be randomly assigned after Rechallenge 1 and before Rechallenge 2:
Group 1: No treatment
Group 2: Upadacitinib by mouth
Group 3: Dupilumab under the skin
4. Rechallenge 2 (Approximately Day 71 to Day 78): DPCP will be given at selected individual

dose, and skin will be assessed at different time points.
5. End of study visit (Day 85): For final assessments.
Study assessments include physical examinations, clinical laboratory tests and vital signs. All side effects will be recorded until the study ends (around 12 weeks).

What are the possible benefits and risks of participating?
Participants will not receive any benefit from taking part in this study, but the information that is learned from the study may help people with autoimmune diseases and cancer in the future.
This is an experimental medicine study. The expected risks for DPCP, based on how the drug works and results from laboratory studies are listed as follows: exaggerated immune response (hypersensitivity), local and systemic (in blood) side effects like skin inflammation caused by direct contact (contact dermatitis), red, itchy welts (urticaria), swelling, redness of skin (erythema), darkening of skin colour (hyperpigmentation) and swelling of lymph node.
The participant information sheet and informed consent form, which will be signed by every participant agreeing to take part in the study, includes a detailed section outlining the risks to participating in the study. Participants may have none, some, or all of the possible side effects listed, and they may be mild, moderate, or severe. To minimise the risk associated with taking part, participants are frequently reviewed for any side effects and other medical events. If they have any side effects or are worried about them, or have any new or unusual symptoms, participants will be encouraged to talk with their study doctor. The study doctor will also be looking out for side effects and will provide appropriate medical care.
There may also be side effects that the researchers do not expect or do not know about and that may be serious. Many side effects go away shortly after the intervention ends. However, sometimes side effects can be serious, long-lasting, or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop the procedure. The study doctor will discuss the best way of managing any side effects with participants. There is always a chance that an unexpected or serious side effect may happen. This can happen to people who take drugs used in this study or any other drug.

Where is the study run from?
Janssen Research & Development, LLC

When is the study starting and how long is it expected to run for?
December 2025 to August 2026

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

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Dr Christina Yeung

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Additional identifiers

Integrated Research Application System (IRAS)
363846

Study information

Scientific Title
An experimental study to assess a diphenylcyclopropenone skin challenge model in healthy participants for the evaluation of immunomodulatory therapies

Acronym
NOPRODPCNAP0003

Study objectives
To study cutaneous inflammatory responses when exposed to diphenylcyclopropenone (DPCP) over time after an initial exposure, by examining the skin of healthy adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 03/12/2025, South Central - Oxford A Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8241; oxforda.rec@hra.nhs.uk), ref: IRAS 363846

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Diphenylcyclopropenone skin challenge models are studied in healthy participants for the evaluation of immunomodulatory therapies

Interventions
Participants will be allocated to a treatment arm according to a randomisation schedule prepared by a statistician at Janssen Research & Development, using an appropriate computer program. We'll allocate participants to group based on their availability and the scheduled trial dates. We'll allocate participant numbers in the order in which participants arrive on the ward and are entered into the study.

Arm 1: DPCP + No Intervention
Participants will undergo sensitization period involving the application of DPCP to elicit a delayed-type hypersensitivity reaction. Following initial sensitization, a dose needed to elicit a response level of "weak positive (+)" or "definitive positive (++)" will be determined. DPCP will be administered at the selected dose in rechallenge 1. Participants in Arm 1 will not receive any

study agent prior to rechallenge 2 and will be exposed to DPCP at the selected dose in rechallenge 2 and will undergo study assessments for up to Day 85.
Diphenylcyclopropenone(DPCP) will be administered topically.

Arm 2: DPCP + Upadacitinib
Participants will undergo sensitization period involving the application of DPCP to elicit a delayed-type hypersensitivity reaction. Following initial sensitization, a dose needed to elicit a response level of "weak positive (+)" or "definitive positive (++)" will be determined. DPCP will be administered at the selected dose in rechallenge 1. Participants will then receive upadacitinib from Day 68 to Day 78, and will undergo rechallenge 2 where DPCP will be administered again at the selected dose followed by study assessments for up to Day 85.
Diphenylcyclopropenone(DPCP) will be administered topically.
Upadacitinib will be administered orally.

Arm 3: DPCP + Dupilumab
Participants will undergo sensitization period involving the application of DPCP to elicit a delayed-type hypersensitivity reaction. Following initial sensitization, a dose needed to elicit a response level of "weak positive (+)" or "definitive positive (++)" will be determined. DPCP will be administered at the selected dose in rechallenge 1. Participants will then receive dupilumab on Day 64, and will undergo rechallenge 2 where DPCP will be administered again at the selected dose followed by study assessments for up to Day 85.
Diphenylcyclopropenone (DPCP) will be administered topically.
Upadacitinib will be administered subcutaneously.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Diphenylcyclopropenone (DPCP), Upadacitinib (RINVOQ), Dupilumab (DUPIXENT)

Primary outcome(s)
1. DPCP- sensitized participants exhibiting skin response (that is, clinical induration, edema and erythema) measured using the International Contact Dermatitis Research Group (ICDRG) grading scale at 48 hours after Rechallenge 1 (that is, from Day 50 up to Day 52)

2. DPCP- sensitized participants exhibiting skin response (that is, clinical in duration, edema and erythema) measured using the ICDRG grading scale at 7 days after Rechallenge 1 (that is, from Day 50 up to Day 57)

3. DPCP-sensitized participants exhibiting skin response (that is, clinical in duration, edema and erythema) measured using the ICDRG grading scale at 48 hours after Rechallenge 2 (that is, from Day 71 up to Day 73)

4. DPCP-sensitized participants exhibiting skin response (that is, clinical in duration, edema and erythema) measured using the ICDRG grading scale after rechallenge 2 at 7 days after Rechallenge 2 (that is, from Day 71 up to Day 78)

Key secondary outcome(s))

Completion date
07/08/2026

Eligibility

Key inclusion criteria
1. Be healthy on the basis of physical examination, medical history, vital signs performed at screening
2. Be healthy on the basis of clinical laboratory tests performed at screening
3. Have a body weight of no less than 50 kg and body mass index within the range of 18 and 30 kg/m^2 (inclusive)
4. During study participation and, if applicable, for 30 days after the last dose of study agent a female participant must:
4.1. Be willing to use highly effective methods of contraception
4.2. Not breastfeed or be pregnant
4.3. Not donate gametes (for example, eggs) or freeze for future use for the purpose of assisted reproduction
4.4. Have a negative highly-sensitive (for example, beta-human chorionic gonadotropin [hCG]) pregnancy test before starting the intervention period and agree to further pregnancy tests
5. Must be a non-smoker/vaper (not smoked/vaped for at least 6 months prior to screening) and has not used nicotine-containing products (for example, nicotine patch) for 3 months prior to screening

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of or current clinically meaningful cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, hematologic, rheumatologic, psychiatric, metabolic, thrombotic or dermatologic disturbances
2. Current or chronic history of non-infectious liver disease
3. History of malignancy before screening
4. Known prior exposure to DPCP, upadacitinib or dupilumab
5. History of severe allergic reaction, angioedema, or anaphylaxis to drugs or food

Date of first enrolment
17/12/2025

Date of final enrolment
15/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Medicines Research (HMR)
Cumberland Avenue
Park Royal
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England
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Sponsor information

Organisation
Janssen Research & Development, LLC

Funder(s)

Funder type

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

IPD sharing plan summary
Not expected to be made available