

A long-term extension study of ustekinumab in pediatric participants with different medical conditions

Submission date 20/01/2023	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/08/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/05/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Ustekinumab is a study drug that has been studied in adult participants with Crohn's disease, ulcerative colitis and psoriatic arthritis. It is now being studied in paediatric participants with the conditions of paediatric Crohn's disease, paediatric ulcerative colitis and juvenile psoriatic arthritis. The purpose of this study is to collect longterm safety data in those paediatric study participants and to provide continued access to the study drug ustekinumab to the paediatric study participants, who in the opinion of the investigator, will continue to benefit from ustekinumab therapy. This study is considered a longterm extension (LTE) study.

Who can participate?

Participants who successfully completed one of four primary studies, aged 2 – 17 years old

What does the study involve?

The study has three parts:

Enrolment visit (W0): eligible participants will sign the informed consent to join the study

Treatment period: participants will be seen at least once every 6 months and continue to take ustekinumab during this time, based on the protocol specified dosing schedule

Safety follow-up visit: participants will be seen 20 weeks after the last administration of ustekinumab

During study visits a variety of tests will be carried out including, but not limited to, vital signs, physical exam, questionnaires and blood and urine samples.

What are the possible benefits and risks of participating?

There is no established benefit to participants of this study. Based on scientific theory, taking ustekinumab may improve the participants' condition (paediatric Crohn's disease, paediatric ulcerative colitis or juvenile psoriatic arthritis). However, this cannot be guaranteed because ustekinumab is still under investigation as a treatment and it is not known whether ustekinumab 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 paediatric Crohn's disease, paediatric ulcerative colitis or juvenile psoriatic arthritis 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 lifethreatening, and they can vary from person to person. The most common, known risks are getting symptoms such as headache, sore throat, tiredness, vomiting or diarrhea after getting the study drug. There are other, less frequent risks. The participant information sheet and informed consent form include a detailed section outlining the known risks of participating in the study.

Where is the study run from?

Janssen-Cilag International NV (Netherlands)

When is the study starting and how long is it expected to run for?

January 2023 to September 2027

Who is funding the study?

Janssen Research & Development

Who is the main contact?

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Contact information

Type(s)

Public, Scientific

Contact name

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Contact details

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Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

2020-004457-76

IRAS number

1005154

ClinicalTrials.gov number

NCT05092269

Secondary identifying numbers

CNTO1275ISD3001, IRAS 1005154, CPMS 52012

Study information

Scientific Title

A Phase III, multicenter, open-label, basket, long-term extension study of ustekinumab in pediatric clinical study participants (2 to <18 years of age)

Acronym

UNITED

Study objectives

Long-term safety data on ustekinumab in pediatric clinical study participants (2 to <18 years of age)

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 09/08/2023, West Midlands - Edgbaston Research Ethics Committee (3rd Floor, Barlow House, Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)2071048248; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0019

Study design

Non-randomized study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment, Safety

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

Moderately to severely active Crohn's disease, moderately to severely active ulcerative colitis, juvenile psoriatic arthritis

Interventions

Participants will have continued access to ustekinumab if they complete the primary parent study (CNTO1275PUC3001, CNTO1275CRD3004) and in the opinion of the investigator will continue to benefit from ustekinumab therapy. Participants will either be given Q8W or Q4W ustekinumab subcutaneously, depending on the regimen that they were receiving in the primary study.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Ustekinumab

Primary outcome measure

1. Adverse events (AEs), serious adverse events (SAEs), AEs leading to discontinuation of study intervention, and AEs of special interest (as determined for each indication)
2. Clinical laboratory hematology and chemistry
3. Injection-site reactions
4. AEs of worsening of the disease under study
5. An addition of concomitant therapy due to loss of response

Collected from patients' medical records from enrolment to the end of study participation

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

18/01/2023

Completion date

29/09/2027

Eligibility

Key inclusion criteria

1. Males or females 2 to <18 years of age, inclusive (at the time of the first administration of study intervention during the LTE)
2. Must have completed the dosing planned in the primary pediatric ustekinumab study
3. Benefit of continued ustekinumab therapy (i.e., a clinical response or clinical remission as

defined in the primary study at the final efficacy last visit of the primary study)

4. Parent(s) (preferably both if available or as per local requirements), legal guardian(s) or their legally acceptable representative must sign an ICF indicating that he or she understands the purpose of, and procedures required for, the study and is willing to allow the child to participate in the study. Assent is also required of children capable of understanding the nature of the study (typically 7 years of age and older) as described in Informed Consent Process in protocol Appendix 3 (Section 10.3). An adolescent who signs the assent form will be given the opportunity to sign an adult ICF at a later visit when they reach the age of majority during the study to indicate that he or she participate in the study.

Please refer to study protocol section 5.1 for full list of inclusion criteria.

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

180

Key exclusion criteria

1. Are pregnant, nursing, or planning pregnancy or fathering a child
2. Have had ANY of (a) confirmed severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2 [COVID-19]) infection (test positive), OR (b) suspected SARS-CoV-2 infection (clinical features without documented test results), OR (c) close contact with a person with known or suspected SARS-CoV-2 infection:

Exception: may be included with a documented negative result for a validated SARS-CoV-2 test

- 2.1. Obtained at least 2 weeks after conditions (a), (b), (c) above (timed from resolution of key clinical features if present, eg, fever, cough, dyspnea)

AND

- 2.2. With absence of ALL conditions (a), (b), (c) above during the period between the negative test result and the baseline study visit

NOTES on COVID-related exclusion:

The field of COVID-related testing (for presence of, and immunity to, the SARS-CoV-2 virus) is rapidly evolving. Additional testing may be performed as part of screening and/or during the study if deemed necessary by the investigator and in accordance with current regulations /guidance from authorities/standards of care

Precaution: for those who may carry a higher risk for severe COVID-19 illness, follow guidance from local health authorities when weighing the potential benefits and risks of enrolling in the study, and during participation in the study (protocol Appendix 8 [Section 10.8]).

3. Any condition for which, in the opinion of the investigator, participation would not be in the

best interest of the participant (e.g., compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments

4. Participants who receive a live vaccination may be permitted to remain in the study, if approved by the sponsor and study intervention is held for a period of time specified by the sponsor. Receipt of a live SARS CoV-2 vaccine (against the virus that causes COVID-19) is not automatically an exclusion criterion and must be discussed with the medical monitor

Please refer to study protocol section 5.2 for full list of exclusion criteria.

Date of first enrolment

22/08/2021

Date of final enrolment

10/02/2026

Locations

Countries of recruitment

Argentina

Belgium

England

France

Germany

Hungary

Italy

Japan

Poland

Russian Federation

Scotland

Spain

Türkiye

United Kingdom

Study participating centre

Royal London Hospital

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London

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Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
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B4 6NH

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
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Study participating centre
Great Ormond Street Hospital
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Study participating centre
Sheffield Childrens Hospital
Western Bank
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S10 2TH

Study participating centre
Southampton General Hospital
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Sponsor information

Organisation

Janssen (Netherlands)

Sponsor details

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Leiden

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Sponsor type

Industry

Website

<https://www.janssen.com/netherlands/>

ROR

<https://ror.org/04cxegr21>

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
4. Submission to regulatory authorities

The results of the study will be available to the wider scientific community via publication in scientific journals and presentation at scientific meetings. Study results will be available to participants via 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

29/09/2028

Individual participant data (IPD) sharing plan

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 <https://yoda.yale.edu/>.

IPD sharing plan summary

Available on request