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

Submission date	Recruitment status	[_] Prospectively registered
20/01/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/08/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2026	Other	[X] 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?
JanssenUKRegistryQueries@its.jnj.com

Contact information

Type(s)
Public, Scientific

Contact name
None - Medical Information and Product Information Enquiry

Contact details
Janssen Research & Development (Janssen-Cilag Ltd), 20 Grenfell Road
Maidenhead
United Kingdom
SL6 1EH
+44(0)800 7318450
medinfo@its.jnj.com

Type(s)
Principal investigator

Contact name
Dr Robert Heuschkel

Contact details
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Additional identifiers

ClinicalTrials.gov (NCT)
NCT05092269

Clinical Trials Information System (CTIS)
2020-004457-76

Integrated Research Application System (IRAS)
1005154

Central Portfolio Management System (CPMS)
52012

Protocol serial number
CNTO1275ISD3001

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

Primary study design
Interventional

Study design
Non-randomized study

Study type(s)
Safety, Treatment

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(s)
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

Key secondary outcome(s)
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Years

Upper age limit
17 Years

Sex
All

Total final enrolment
0

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
United Kingdom

England

Scotland

Argentina

Belgium

France

Germany

Hungary

Italy

Japan

Poland

Russian Federation

Spain

Türkiye

Study participating centre
Royal London Hospital
Whitechapel Road
London
England
E1 1FR

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

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Great Ormond Street Hospital
Great Ormond Street
London
England
WC1N 3JH

Study participating centre
Sheffield Childrens Hospital
Western Bank
Sheffield
England
S10 2TH

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Sponsor information

Organisation

Janssen (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

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