A Phase 3 Multicenter, Open-label Study to Evaluate the Efficacy, Pharmacokinetics, Safety, and Immunogenicity of Subcutaneously Administered Ustekinumab or Guselkumab in Pediatric Participants With Active Juvenile Psoriatic Arthritis

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This study has been transitioned to CTIS with ID 2023-507144-36-00 check the CTIS register for the current data. Primary:Evaluate PK and efficacy of ustekinumab and guselkumab in jPsA. Secondary:Evaluate safety of ustekinumab and guselkumab in...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53596

Source
ToetsingOnline

Brief title
(PSUMMIT-Jr)

Condition

- Other condition

Synonym
chronic inflammatory disease, Psoriatic arthritis

Health condition

Skin and Connective Tissue Disease

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Guselkumab, Psoriatic Arthritis, Ustekinumab

Outcome measures

Primary outcome

Ustekinumab Primary:

- Steady-state trough concentrations and population PK model-predicted AUCss

over a 12-week dosing interval at Week 28 by baseline age groups.

- ACR Pedi 30 responses at Week 24

Guselkumab Primary:

- Steady-state trough concentrations and population PK model-predicted AUCss

over a dosing interval (4 or 8 weeks) at Week 28 by baseline age groups.

- ACR Pedi 30 responses at Week 24

Secondary outcome

Ustekinumab Secondary:

- Steady-state trough concentrations and population PK model-predicted AUCss

over a 12-week dosing interval at Week 52 by baseline age groups.

- ACR Pedi 30 response at Weeks 4, 8, 12, 16, and 52

- ACR Pedi 50 and 70 responses at Weeks 4, 8, 12, 16, 24, and 52

- Time to response measured as time to achieving ACR Pedi 30 from baseline through Week 24.

- Change from baseline in cJADAS 10, JADAS 10, 27, and 71 at Weeks 4, 8, 12, 16, 24, and 52.

- Change from baseline in PASI score at Week 24 among the participants with >=3% BSA psoriatic involvement and a PGA psoriasis score of >=2 (mild) at baseline.

- The occurrences and type of AEs, SAEs, and reasonably related AEs.

- The overall incidence of antibodies to ustekinumab (including peak titers) through Week 68.

Guselkumab Secondary:

- Steady-state trough concentrations and population PK model-predicted AUCss over a dosing interval (4 or 8 weeks) at Week 52 by baseline age groups.

- ACR Pedi 30 response at Weeks 4, 8, 12, 16, and 52.

- ACR Pedi 50 and 70 responses at Weeks 4, 8, 12, 16, 24, and 52.

- Time to response measured as time to achieving ACR Pedi 30 from baseline through Week 24.

- Change from baseline in cJADAS 10, JADAS 10, 27, and 71 at Weeks 4, 8, 12, 16, 24, and 52.

- Change from baseline in PASI score at Week 24 among the participants with >=3% BSA psoriatic involvement and a PGA psoriasis

score of >=2 (mild) at baseline.

- The occurrences and type of AEs, SAEs, and reasonably related AEs.

- The overall incidence of antibodies to guselkumab (including peak titers)

through Week 68.

Study description

Background summary

Juvenile psoriatic arthritis (JPsA) is a condition that causes joint inflammation (pain, swelling) and a build-up of cells which form patches of irritated skin due to an over-reaction of the immune system (the body*s defense system, which fights infection).
This a Phase 3 study. This means that the study drug has already been tested in small numbers of healthy volunteers, and in patients with medical conditions, including JPsA. This study is now testing a larger group of patients with JPsA.

Study objective

This study has been transitioned to CTIS with ID 2023-507144-36-00 check the CTIS register for the current data.

Primary:
Evaluate PK and efficacy of ustekinumab and guselkumab in jPsA.

Secondary:
Evaluate safety of ustekinumab and guselkumab in jPsA
Evaluate immunogenicity of ustekinumab and guselkumab in jPsA

Study design

A global Phase 3, open-label, multicenter study.

Intervention

Subjects will be treated for 52 weeks with study drugs.
For this study we make 2 groups:
• Group 1. The people in this group receive Ustekinumab. They will have 9 visits for health exams and tests. They will take ustekinumab at Week 0, 4, 16, 28, 40 and 52. A total of 6 doses of ustekinumab.
• Group 2. The people in this group receive Guselkumab. Guselkumab can be given

every 8 weeks, as determined by the study doctor. They will have 8 visits for health exams and tests. They will take guselkumab at Week 0, Week 4 and then every 8 weeks through week 52.

Subjects and their study doctor will determine which study medicine is best for use.

All patients in this study will get either ustekinumab or guselkumab. During the study, subjects and the study staff will know that they are receiving the study medicine.

The liquid study medicine is given in shot. The needle is put just under the skin, subcutaneously (SC) in the lower stomach area, front of thigh, back of upper arms or buttocks

Study burden and risks

Subjects will participate in the study for up to 68 weeks. Subjects will need to come to the hospital more often than they normally would and they undergo additional tests. These include physical examination; measurement of vital signs; urine tests; an eye exam, answer questionnaires and an investigation of medical history. During the study, participants in Group 1 will receive ustekinumab at Week 0, 4, 16, 28, 40 and 52. A total of 6 doses of ustekinumab. Participants in Group 2 will receive guselkumab at Week 0 then every 4 or 8 weeks through week 52.

Risks associated with the study drugs include allergic reactions (including rash or raised, itchy bumps and serious allergic reactions that could be life-threatening) and side effects (Infections of the nose, sinuses, airways or throat, infections such as herpes simplex infections and fungal skin infections, gastroenteritis, rash, pain at drug injection site, hives, allergic reactions, decreased white blood cells, hives, swelling and depression).

In conclusion, the risks identified from non-clincal and clinical studies show an increased clinical benefit is expected from treatment with the study drugs. Guselkumab and ustekinumab have an overall favorable benefit-risk profile supporting further continued development of the study drug for patients with juvenile psoriatic arthritis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. >=5 to <18 years of age, inclusive.
2. Diagnosis of jPsA by Vancouver inclusion criteria, with exclusion of ERA. Diagnosis made >= 3 months (ie. 90 days) prior to screening. Arthritis plus psoriasis, or arthritis plus >=2 of the following: dactylitis, nail pits, family history of psioriasis in a first or second-degree relative, psoriasis-like rash.
3. Active disease in >=3 joints at screening and at Week 0 (defined as swelling or loss of motion with pain and/or tenderness). Swelling alone meets the criteria for an active arthritic joint. In the absence of swelling, loss of motion with pain or tenderness or both pain and tenderness meet the criteria for an active arthritic joint.
4. Medically stable on the basis of physical examination, medical history, and vital signs performed at screening. Any abnormalities must be determination must be recorded in the participant's source documents and initialed by the investigator.
5. Medically stable on the basis of clinical laboratory tests performed at screening. If the results of the serum chemistry panel or hematology are

outside the normal reference ranges, the participant may be included only if the investigator judges the abnormalities or deviations from normal to not be clinically significant or to be appropriate and reasonable for the population under study. This determination must be recorded in the participant's source documents and initialed by the
investigator.

Exclusion criteria

1. Participants with enthesitis-related arthritis (ERA; see definition in Appendix 17 of the study protocol)
2. Taken any disallowed therapies as noted in Section 6.8, Concomitant Therapy within the timeframe specified before the planned first dose of study intervention.
3. If participants were non-responders to previously received IL-23 blockers including guselkumab, tildrakizumab (MK3222) and risankizumab (BI-655066). Prior non-response to an anti-TNFα inhibitor, an IL-17 inhibitor or a Janus kinase (JAK) inhibitor is not an exclusion.
Participants who previously discontinued ustekinumab for intolerance or inadequate response may be enrolled into the guselkumab cohort.
Patients who previously discontinued guselkumab due to intolerance may be enrolled into the ustekinumab cohort. Participants who previously discontinued tildrakizumab or risankizumab due to
intolerance may be enrolled into either cohort.
4. Received an investigational intervention (including investigational vaccines) or used an invasive investigational medical device within 4 weeks or 5 half-lives (whichever is longer) before the planned first dose of either study intervention or is currently enrolled in another study using an investigational intervention or procedure. Receipt of an investigational vaccine for COVID-19 is not an automatic exclusion criterion; discuss with medical monitor.
5. Have a history of latent or active granulomatous infection, including TB, histoplasmosis, or coccidioidomycosis, prior to screening. An exception is made for participants currently receiving treatment for latent TB with no evidence of active TB, or who have a history of latent TB and documentation of having completed appropriate treatment for latent TB prior to the first administration of either study intervention (Section 5.2, Exclusion criterion 14b of the study protocol).

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-07-2023
Enrollment:	2
Type:	Anticipated

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Guselkumab
Generic name:	Guselkumab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	STELARA
Generic name:	Ustekinumab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	20-02-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-05-2023

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-01-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-01-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2023-507144-36-00
EudraCT	EUCTR2020-005503-40-NL
ClinicalTrials.gov	NCT05083182
CCMO	NL83457.100.23