A three-part randomized, double-blind, placebo-controlled study to investigate the efficacy and safety of secukinumab treatment in Juvenile Idiopathic arthritis subtypes of psoriatic and enthesitis-related arthritis

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Ethical review	Not approved
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON45692

Source
ToetsingOnline

Brief title
CAIN457F2304

Condition

- Autoimmune disorders

Synonym
Joint inflammation, rash

Research involving

Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (sponsor/verrichter van dit onderzoek)

Intervention

Keyword: enthesitis juvenile arthritis, placebo-controlled, psoriatic artritis, secukinumab

Outcome measures

Primary outcome

To demonstrate that the time to flare in Treatment Period 2 is longer with

secukinumab for combined ERA and JPsA groups than with placebo

Secondary outcome

1. To evaluate the effect of secukinumab treatment for all patients and each

JIA category in Treatment Period 1 up to Week 12 (end of Treatment period 1)

with respect to:

* JIA ACR (American College of Rheumatology) 30/50/70/90/100and inactive

disease status

* Each JIA ACR core component

* Change from baseline Juvenile Arthritis Disease Activity Score (JADAS)

* Total enthesitis count

* Total dactylitis count

2. To evaluate withdrawal effect of secukinumab treatment for all patients and

each JIA category during and at the end of Treatment Period 2

with respect to:

* JIA ACR 30/50/70/90/100 and inactive disease status

3. To evaluate Pharmacokinetics (PK) of secukinumab and confirm the predicted

dose in Treatment Period 1

4. To evaluate the safety/tolerability and immunogenicity of Secukinumab

Study description

Background summary

Secukinumab (AIN457) is a high-affinity fully human monoclonal anti-human antibody that targets IL-17A and neutralizes activity. Secukinumab treatment has demonstrated significant and clinically meaningful efficacy in treating adults with ankylosing spondylitis (AS) and
psoriatic arthritis (PsA), both approved indications.
The adult AS and PsA secukinumab data support the proposed secukinumab study in children with similar pediatric spondyloarthritic conditions: ERA and JPsA.
This study will investigate secukinumab treatment in children * 2 to < 18 years of age with active JPsA or ERA JIA using
a pediatric dose equivalent to the adult 150mg dose.

Study objective

The purpose of the study is to investigate the use of secukinumab (AIN457) treat ment in children from 2 to18 years of age with either active Enthesitis -Related Arthritis (ERA) or Juvenile Psoriatic Arthritis (JPsA) subtypes of Juvenile Idiopathic Arthritis (JIA). The study aims to demonstrate the efficacy of secukinumab (AIN457) treatment to prevent a disease flare (worsening) during a double-blind placebo-control treatment withdrawal part of the trial.

Study design

There are three parts to this study. If the patient meets the requirements to continue participation in the study, he/she will enter Treatment Period 1. In this part of the study, all children will receive the medication secukinumab (AIN457). The patient will receive this medication once a week for the first month, then every 4 weeks until Week12.
At Week 12, your child will be assessed to see if he/she has adequately responded to the medication. If he/she has not, then he/she will not receive any more study medication and not go into Treatment Period 2. Instead, he/she will be asked to undergo a 12-week post-treatment
follow-up and then leave the study. During this period, your child will not receive any study drug, but the Study Doctor will continue to check on your child*s health.

If the patient does respond adequately to the medication, he/she will enter Treatment Period 2. During Treatment Period 2, the patient will be randomized to receive either secukinumab (AIN457) or a placebo every 4 weeks, starting at Week 12.
If during Treatment Period 2 the patient experiences a disease flare , then the patient will immediately enter Treatment Period 3, and will receive (or continue to receive) on the same day the medication secukinumab (AIN457). Once 33 children in Treatment Period 2 have experienced a disease flare, all children in the study will move into Treatment Period 3.
In Treatment Period 3 all children will receive secukinumab (AIN457) just as they had in Treatment Period 1. The treatment portion of the study will finish at Week 104 (2 years) and then the children will either enter a follow up period lasting 12 weeks from last stud drug administration.

Intervention

Investigational treatment:
* Secukinumab 150mg/1mL, liquid formulation provided in 1 mL PFS (Pre-filled syringe)
* Secukinumab 75mg/0.5mL, liquid formulation provided in 0.5 mL PFS
Reference treatment
* Placebo, liquid formulation in a 1 mL and 0.5 mL PFS

Study burden and risks

Possible common side effects reported in adult patients with psoriasis, psoriatic arthritis or ankylosing spondylitis who participated in studies treated with secukinumab treatment include:
* Upper respiratory tract infections/disorders such as a common cold
* Diarrhea
* Urticaria (hives)
More uncommon side effects include:
* Conjunctivitis (inflammation of the white part of the eye, usually due to an infection)
* Neutropenia (low number of a special type of white blood cell which is part of the immune system)
* Oral candidiasis (oral thrush; a fungal infection involving the mouth)

Although secukinumab is a marketed drug for adult patients with psoriasis, psoriatic arthritis or ankylosing spondylitis, it has not yet been tested in children with Juvenile psoriatic arthritis (JPsA) or enthesitis-related arthritis (ERA). Consequently, not all of the potential side effects are known at this time for children who have JPsA or ERA treated with secukinumab.
The risks of collecting blood may include fainting, pain and/or bruising. Rarely, these may be a small blood clot or infection at the site of the needle puncture.

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

- Confirmed diagnosis of Enthesitis-related arthritis (ERA) or Juvenile psoriatic arthritis (JPsA) according to the international League of Associations for Rheumatology (ILAR) classification criteria of at least 6 months duration.
- Active disease (ERA or JPsA) defined as having both:
at least 3 active joints
at least 1 site of active enthesitis at baseline or documented by history.
- Inadequate response (at least 1 month) or intolerance to at least 1 nonsteroidal anti-inflammatory drugs (NSAID)
- Inadequate response (at least 2 months) or intolerance to at least 1 Disease-modifying antirheumatic drugs (DMARD)
- No concomitant use of second line agents such as disease-modifying and/or

immunosuppressive drugs.

Exclusion criteria

- Patients fulfilling any ILAR diagnostic JIA category other than ERA or JPsA.
- Patients who have ever received biologic immunomodulating agents.
- Patients taking any non-biologic DMARD except for MTX (or sulfasalazine for ERA patients only).
- Patients with active uncontrolled inflammatory bowel disease or active uncontrolled uveitis.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	4
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Cosyntyx
Generic name:	secukinumab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-01-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Not approved Date:	18-09-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2016-003761-26-NL
ClinicalTrials.gov	NCT03031782
CCMO	NL59675.041.16