An extension study to evaluate the sustainability of clinical benefits, safety and tolerability of secukinumab in patients with active Ankylosing Spondylitis (CAIN457F2305E1)

Published: 26-09-2013
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Primary: To evaluate the sustainability of subject benefits as quantified by the ASAS20 during long-term treatment.Secondary: ASAS40, safety and tolerability.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON44667

Source
ToetsingOnline

Brief title
CAIN457F2305E1

Condition

- Joint disorders

Synonym
ankylosing spondylitis

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma BV

Intervention

Keyword: ankylosing spondylitis, longterm, safety, secukinumab

Outcome measures

Primary outcome

ASAS20.

Secondary outcome

ASAS40, adverse events.

Study description

Background summary

This is an extension study for subjects who have completed the study CAIN457F2305 (MEC 2011-184, NL37069.018.11, A randomized, double-blind, placebo-controlled, multicenter study of secukinumab to demonstrate the efficacy at 16 weeks and to assess the long term safety, tolerability and efficacy up to 2 years in patients with active Ankylosing Spondylitis).
By joining the study subjects can continue treatment with secukinumab. In this study the long term effects of the drug will be investigated. All subjects will be treated with active study drug.

Study objective

Primary: To evaluate the sustainability of subject benefits as quantified by the ASAS20 during long-term treatment.
Secondary: ASAS40, safety and tolerability.

Study design

Multicenter phase III parallel-group extension study. Double blind, unblinding after 1st year.
Continuation of secukinumab dose during previous study:
• Secukinumab 75 mg (s.c. injections every 4 weeks)

• Secukinumab 150 mg (s.c. injections every 4 weeks)
Patients will, in principle, self-inject the drug with prefilled syringes.
Treatment period approx. 3 years.
Independent DSMB.
Approx. 300 patients.

Intervention

Treatment with secukinumab.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: Study duration approx. 3 years. Approx. 16 visits. Duration max.3 h.
Fasting 6x.
Every 4 weeks 2 s.c. injections (1st year because of double-blind double-dummy design) or 1 s.c. injection (after 1st year).
For those subjects who do not self-inject: approx. 25 extra short visits for injection(s).
Every visit: physical examination, blood tests 5-30 ml/occasion, urine tests.
Every 6 months: ECG.
X rays spine: 1x.
MRI scan (subset of patients) 2x.
Questionnaires: visual analogue scales: disease activity, pain, BASFI, BASDAI, FACIT-Fatigue, SF-36.

Contacts

Public
Novartis

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NL
Scientific
Novartis

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Subjects must have completed the core study
• Subjects who are deemed by the investigator to benefit from continued secukinumab therapy

Exclusion criteria

• Any subject taking other concomitant biologic immunomodulating agent(s) except secukinumab during the core study
• Pregnancy, lactation.
• Women of childbearing potential who do not use adequate contraception.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2013
Enrollment:	9
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	26-09-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	16-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	29-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2013-001089-40-NL
ClinicalTrials.gov	NCT01863732

Register	ID
CCMO	NL45662.018.13