A randomized, multicenter Study to evaluate the Effect of secukinumab 300 mg s.c. administered during 52 Weeks to patients suffering from new-onset moderate to severe plaque Psoriasis as early Intervention compared to standard treatment with narrow band UVB (STEPin study)

Published: 14-11-2016
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Ethical review	Not approved
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON43019

Source
ToetsingOnline

Brief title
STEPin

Condition

- Epidermal and dermal conditions

Synonym
plaque psoriasis, psoriasis vulgaris

Research involving
Human

Sponsors and support

Primary sponsor: TFS Trial Form Support BV
Source(s) of monetary or material Support: Novartis

Intervention

Keyword: narrow-band UVB, PASI, Psoriasis, secukinumab

Outcome measures

Primary outcome

To demonstrate that early treatment with secukinumab 300 mg s.c. (Arm A1) is superior to standard of care treatment with nb-UVB (Arm B1) in patients with new-onset moderate to severe psoriasis with respect to patients achieving * 90% improvement (reduction) in psoriasis area and severity index (PASI 90) response at Week 52.

Secondary outcome

To evaluate the superiority of early treatment with secukinumab (Arm A1) versus nb-UVB (Arm B1) based on the proportion of all randomized patients who achieve at least PASI 90 at Week 104.

Study description

Background summary

A randomized, multicenter STudy to evaluate the Effect of secukinumab 300 mg s.c. administered during 52 weeks to patients suffering from new-onset moderate to severe plaque Psoriasis as early Intervention compared to standard treatment

with narrow band UVB (STEPIn study).

There is evidence that treatment of psoriasis during the first years is conservative and frequently based on topical agents which rarely clear lesions completely. Treatment with biologic systemic agents is often initiated only when topical agents, phototherapy and conventional systemic treatment have proved to be inadequate, even in patients with moderate to severe disease. inhibition of IL-17A early after disease onset may be a novel and important therapeutic approach interfering with the immune system before the establishment of extensive and chronic inflammation.

Study objective

The purpose of this study is to determine whether early intervention with subcutaneous (s.c.) secukinumab 300 mg in patients with new-onset moderate to severe psoriasis may lead to prolonged symptom-free periods by preventing reactivation of old lesions or ultimately totally hindering the occurrence of new lesions, i.e., changing the natural course of the disease (Main Study).

Primary objective: To demonstrate that early treatment with secukinumab 300 mg s.c. (Arm A1) is superior to standard of care treatment with nb-UVB (Arm B1) in patients with new-onset moderate to severe psoriasis with respect to patients achieving * 90% improvement (reduction) in psoriasis area and severity index (PASI 90) response at Week 52.

Key secondary objective: To evaluate the superiority of early treatment with secukinumab (Arm A1) versus nb-UVB (Arm B1) based on the proportion of all randomized patients who achieve at least PASI 90 at Week 104.

Study design

The design consists of the Main Study (with 3 clinical epochs: Screening Epoch, Treatment Epoch, and Follow-up Epoch) and a Mechanistic Sub-study (with 2 epochs: Screening Epoch and Treatment Epoch).

The Main Study is multicenter, randomized, 2-treatment-arm (secukinumab and nb-UVB), parallel-group and not blinded.

The Mechanistic Sub-study comprises 5 treatment arms (A1b, A2, B1, C1, and C2).

Intervention

Secukinumab (AIN457) 300 mg
Narrow-band UVB

Study burden and risks

Risks:
Secukinumab has the potential to increase the risk of infections. In clinical studies, infections (e.g., nasopharyngitis, upper respiratory tract infections, oral herpes, pharyngitis, sinusitis, tinea pedis, conjunctivitis, tonsillitis, oral candidiasis) have been observed in patients receiving secukinumab. Most of these were mild or moderate.

The main risk derived from the treatment with nb-UVB is the occurrence of *sun burn* leading to itching, irritation, redness of the skin, and tanning. Calcipotriol (component of the combination product calcipotriol 50 *g/g and betamethasone 0.5 mg/g), which is given for the first 4 weeks of each cycle of nb-UVB, may also cause redness and itching. The risk of skin cancer is considered minimal.

The risk to study patients will be minimized by complying with the eligibility criteria and study procedures and close clinical monitoring.

Burden:
Psoriasis area severity index scores outcome measures, the assessment of the severity of the psoriasis symptoms and the extent to which the patient*s body area is affected by the disease, is mandated by the EMA for the clinical investigation of medicinal products for the treatment of psoriasis.

Benefits:
The current hypothesis is that early intensive intervention with biological drugs in the autoimmune process dampens the immune mechanism that leads to a chronic inflammatory disease. In rheumatoid arthritis it has been shown that early intervention can modify disease activity (in particular bone erosion) and severity outcomes.
The potential benefits of early intensive intervention with secukinumab may result in quick clearance of psoriatic plaques and prolong relapse-free periods or complete prevention of relapses. Patients may benefit from 1 or 2 years of treatment that has been proven to be effective for at least 1 year.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Aged 18 to 40 years inclusive
* moderate to severe plaque psoriasis with either new onset or lasting for at least 5 years.
Additional inclusion criteria may apply , please refer to the protocol.

Exclusion criteria

* Forms of psoriasis other than plaque-type (e.g., pustular, erythrodermic, guttate, light sensitive, drug induced) ;* Ongoing use of prohibited treatments;* Pregnant or nursing (lactating) women ;* Women of child-bearing potential not willing to use contraception;*Active ongoing inflammatory diseases other than psoriasis or psoriatic arthritis that might confound the evaluation of the benefit of secukinumab therapy ;Additional exclusion criteria may apply , please refer to the protocol.

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	14-11-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-02-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Not approved Date:	07-09-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
Other	ClinicalTrials.gov
EudraCT	EUCTR2015-002423-26-NL
CCMO	NL56681.091.16