

PROSPECT: Observational, descriptive study of PRior and concomitant psoriasis treatments in patients receiving Secukinumab in the routine treatment of moderate to severe plaque-type psoriasis

First published: 19/08/2015

Last updated: 02/07/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS10715

Study ID

38173

DARWIN EU® study

No

Study countries

☐ Germany

Study description

It is expected that in routine treatment of psoriasis, due to the current recommendations and medical practice, transition periods before administration of Secukinumab will be short. Also, some concomitant treatments with pharmacologically active substances will be given in parallel, tapered or stopped only after the effectiveness of Secukinumab in the individual patient becomes evident, despite lack of experience in their combined application. The objective of this descriptive study is to assess prior and concomitant psoriasis treatments in patients receiving Secukinumab in the routine treatment of moderate to severe plaque-type psoriasis, focusing on duration of transition periods from prior treatments to Secukinumab and on the use of concomitant treatments. Furthermore, effectiveness as assessed in clinical routine as well as safety will be described. This is a single-cohort, non-interventional study with a study duration of 24 weeks recruiting patients for whom the decision of treatment with Secukinumab for plaque-psoriasis has been made before inclusion. It is expected that most patients are likely to be seen at the regular visits at weeks 0, 4, 12, 16, and 24 and that some patients may also be seen at some of the additional visits at weeks 1, 2, 3, 8, and 20. The study population will consist of a representative group of adults with moderate to severe plaque type psoriasis who are candidates for systemic therapy and for whom routine treatment with Secukinumab is planned. The goal is to recruit a total of approximately 1200 patients in approximately 300-400 sites in Germany.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Multiple centres: 300 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Laura Hagan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2015

Actual: 16/07/2015

Study start date

Planned: 01/09/2015

Actual: 27/08/2015

Data analysis start date

Planned: 30/06/2016

Date of interim report, if expected

Planned: 31/12/2016

Date of final study report

Planned: 30/09/2018

Actual: 31/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals AG

Study protocol

[PROSPECT-NIS Protocol Final Redacted 2015-06-18.pdf](#)(440.79 KB)

[CAIN457ADE07_PROSPECT-NIS_Protocol_Am1_2016-05-13_clean_redacted.pdf](#)
(441.8 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers
and links

CAIN457ADE07

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Other

Safety study (incl. comparative)

If 'other', further details on the scope of the study

Drug interactions

Data collection methods:

Primary data collection

Main study objective:

The objective of this descriptive study - without any formal a priori hypothesis - is to assess prior and concomitant psoriasis treatments in patients receiving Secukinumab in the routine treatment of moderate to severe plaque-type psoriasis, focusing on duration of transition periods from prior treatments to Secukinumab and on the use of concomitant treatments as well as effectiveness and safety.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Drug interaction study, Observational study, Post authorization safety study (PASS)

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name
SECUKINUMAB

Additional medical condition(s)

Plaque type psoriasis (MedDRA 6.0, LLT: 10050576)

Population studied

Short description of the study population

The study population will consist of a representative group of adults with moderate to severe plaque type psoriasis who are candidates for systemic therapy and for whom routine treatment with Secukinumab is planned. The goal is to recruit a total of approximately 2504 patients in approximately 300-400 sites in Germany.

Inclusion Criteria

Patients eligible for inclusion in this study have to fulfill all of the following criteria at baseline (Visit 1, week 0):

1. Patients must give a written, signed and dated informed consent before documentation in the study will be commenced.
2. Men or women must be at least 18 years of age.
3. Diagnosis of clinically moderate to severe plaque-psoriasis. Other forms of psoriasis may be present if moderate to severe plaque-psoriasis is the reason for Secukinumab treatment.
4. Candidates for systemic therapy.
5. Documented decision for treatment with marketed Secukinumab in compliance with the prescribing information and the summary of product characteristics.
6. Initial treatment with marketed Secukinumab planned for the day of the

baseline visit.

Exclusion Criteria

Patients fulfilling any of the following criteria at baseline (Visit 1, week 0) are not eligible for inclusion in this study. Conditional exclusion criteria will be activated during the course of the study as soon as predefined recruitment criteria have been met without the need for a protocol amendment. No additional exclusion criteria may be applied by the treating physician, in order to ensure that the study population will be representative of all eligible patients.

1. Initial treatment with marketed Secukinumab prior to the day of informed consent.
2. Parallel enrollment in any interventional clinical trial.
3. Parallel enrollment in a non-interventional study sponsored by Novartis or one of her divisions or affiliates.
4. After 300 patients who had participated in a clinical trial with Secukinumab prior to inclusion in this NIS have been recruited, no further patient

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Immunocompromised

Estimated number of subjects

2405

Study design details

Outcomes

The descriptive primary endpoint of the study is the assessment of the duration of the transition periods from prior treatments to Secukinumab with adequate precision for the following prior treatment categories and groups: • All topical treatments • All conventional systemic treatments (and phototherapy) • All biologic treatments • Fumaric acid esters • Methotrexate • Ciclosporin, • Assessment of transition duration for other prior treatment groups • Proportion of patients in different categories of transition periods related to treatment intervals and systemic terminal half-lives • Relative dose tapering and dose of concomitant treatments • Effectiveness as assessed by PASI and other routine parameters • Safety as assessed in routine treatment (AEs and SAEs)

Data analysis plan

The data will be analyzed by Novartis and/or by the designated CRO. All data will be analyzed descriptively. The duration of transition periods will be described by the arithmetic mean, standard deviation, median, inter-quartile range and 95% confidence interval for all relevant treatment categories and groups. Proportions of patients within certain categories of transition periods will be calculated with 95% confidence intervals and displayed by stacked bar plots. Summary statistics will be presented for all other outcome measures. After 800 patients have been recruited, an interim analysis of the baseline data will determine, whether sufficient precision for all groups of previous treatments is likely to be achieved. If necessary, the study sample size will be adjusted via a protocol amendment to obtain adequate and representative coverage of all previous treatment groups. AMENDMENT I: Sample size = 2504, a compromise between feasible sample size and an adequate precision

Documents

Study results

[CAIN457ADE07_final CSR_report_V1.0_190131_2_Redacted.pdf](#)(803.85 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

[Other](#)

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No