

# 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.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

Novartis Pharmaceuticals

**First published:** 01/02/2024

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Institution

Multiple centres: 300 centres are involved in the study

## Contact details

### **Study institution contact**

Laura Hagan Trialandresults.registries@novartis.com

Study contact

[Trialandresults.registries@novartis.com](mailto:Trialandresults.registries@novartis.com)

### **Primary lead investigator**

Laura Hagan

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 01/06/2015

Actual: 16/07/2015

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### **Study start date**

Planned: 01/09/2015

Actual: 27/08/2015

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### **Data analysis start date**

Planned: 30/06/2016

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### **Date of interim report, if expected**

Planned: 31/12/2016

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### **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

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**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

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**Study type:**

Non-interventional study

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**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

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**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

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**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

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**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

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#### 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)

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#### Special population of interest

Immunocompromised

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#### 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)

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## **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)

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## 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

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No