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

First published: 19/08/2015
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/38173

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 institution and networks

Institutions

Novartis Pharmaceuticals
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Institution

Multiple centres: 300 centres are involved in the study

Contact details

Study institution contact
Laura Hagan
Study contact

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

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 patien

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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)

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

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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.AMEMNDMENT I: Sample size = 2504, an 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

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