Prospective, multicentric, national,observational cohort of patients receiving a systemic treatment for psoriasis

First published: 27/01/2020

Last updated: 11/02/2022

Study Finalised

Administrative details

EU PAS number

EUPAS32946

Study ID

45731

DARWIN EU® study

No

Study countries

France

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 23 centres are involved in the study

Contact details

Study institution contact

Olivier Chosidow RA-RNDUS-ClnclTrlsEU@its.jnj.com

Study contact

RA-RNDUS-ClnclTrlsEU@its.jnj.com

Primary lead investigator

Olivier Chosidow

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/02/2012

Study start date

Actual: 07/11/2012

Date of final study report

Planned: 31/12/2021

Actual: 22/10/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

Document the real life benefit of biologic treatments in psoriasis in French adult patients in France: clinical efficacy, quality of life efficacy, safety profile, drug use

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

STELARA

Population studied

Short description of the study population

Patients receiving a systemic treatment for psoriasis.

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

280

Study design details

Outcomes

1.Determine patient Initiating Treatment with guselkumab: Socio-demographic Data, comorbidities, disease history. 2.Prescribing information. 3.Therapeutic strategy. 4. Effectiveness: clinical outcomes, duration of maintenance of the therapeutic benefit5. Safety data: incidence of adverse events (AE) and serious adverse events (SAE)

Data analysis plan

Statistical analysis will start with a descriptive analysis. Patient characteristics are described in a descriptive manner and compared to RCT data to show comparability between patients Efficacy analysis is performed on the total population Persistency analysis is performed in a survival analysis on the overall period of evaluation.

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