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

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45731

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

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Study contact

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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

Name of medicine

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

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