Retrospective chart review to assess the effectiveness of the Skilarence® risk minimisation activities in daily practice – a post-authorisation safety study (PASS) (RETROSKIL)

First published: 23/12/2019

Last updated: 20/09/2023

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37187

EU PAS number

EUPAS29842

Study ID

37187

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] United Kingdom

Study description

The aim of this PASS is to assess the effectiveness of risk minimisation measures for Skilarence® in daily clinical practice. The Summary of Product Characteristics (SmPC) and an educational programme aim to inform health care professionals about the risk of serious opportunistic infections such as progressive multifocal leukoencephalopathy (PML), associated with the use of Skilarence® and to provide guidance on how to minimise and manage this risk through appropriate monitoring of lymphocyte and leukocyte count abnormalities.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Faber Susanne

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/06/2018

Actual: 15/06/2018

Study start date
Planned: 30/06/2019

Actual: 23/03/2021

Data analysis start date
Actual: 23/12/2021

Date of final study report
Planned: 31/12/2020

Actual: 15/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Almirall S.A

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess the effectiveness of risk minimisation measures for Skilarence® in daily clinical practice. The Summary of Product Characteristics (SmPC) and an educational programme aim to inform HCPs about the risk of serious opportunistic infections such as PML, associated with the use of Skilarence® and to provide guidance on how to minimise and manage this risk through appropriate monitoring of lym

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective Chart Review (RCR)

Study drug and medical condition

Name of medicine

SKILARENCE

Population studied

Short description of the study population

The study population included patients treated with Skilarence® under routine clinical practice.

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)

Estimated number of subjects

173

Study design details

Outcomes

Number of patients who adhere to the appropriate monitoring of lymphocyte and leukocyte counts and who comply with the associated actions to be taken with regard to Skilarence® treatment as described in the SmPC and as detailed in the educational material. Patient characteristics of interest: Demographics (age, sex), BMI, smoking status, alcohol use, Baseline comorbidities, Comedications at baseline Disease characteristics. Average starting dose and

average maintenance dose of Skilarence® based on physicians’ prescriptions Number of patients with recorded diagnosis of serious infections Number of patients with ADRs and SADRs

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Data analysis plan

All analyses are exploratory and descriptive in nature and will be performed using epidemiological methods as appropriate. Categorical variables will be analysed by frequency tables (absolute and relative frequencies) and continuous variables by summary statistics (mean, standard deviation, median, minimum, maximum, and quartiles). For categorical variables changes from baseline will be presented in shift tables. Due to the nature of the data sources and the non-interventional approach, missing and inconsistent data will occur and will be considered in the analysis and the assessment of the results. All analyses will be performed overall and for each country separately. Depending on scientific interest and the distribution of the data, subsequent exploratory analyses may be performed.

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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