Retrospective non-interventional chart review study of the clinical outcomes of guselkumab in the treatment of Finnish patients with plaque psoriasis (FINGUS)

First published: 05/02/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS39376

Study ID

39377

DARWIN EU® study

No

Study countries

☐ Finland

Study description

The study is an observational, retrospective, non-interventional patient chart review study, whose population is Finnish adult patients with confirmed diagnosis of plaque psoriasis (PSO) who have been initiated with guselkumab treatment between 1st December 2017 and 1st december 2019. The primary objective of the study is to investigate the real-life clinical outcomes, and drug survival of gusekumab treatment. The secondary objectives are to characterize the patients who initiated guselkumab treatment during the study timeline, to assess the dosing interval of guselkumab during the induction and maintenance phase of the treatment, to assess the reasons for discontinuation of guselkumab, and to estimate the patients' quality of life through DLQI, if available.

Study status

Finalised

Research institutions and networks

Institutions

Tampere University Hospital

Finland

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Tampere university hospital Tampere Finland, Vaasa central hospital Vaasa Finland, Kuopio university hospital Kuopio Finland, Lohja hospital (HUS) Lohja Finland,
Mikkeli central hospital Mikkeli Finland, Turku university central hospital Turku Finland, Ahvenanmaa central hospital Ahvenanmaa Finland, Helsinki university hospital Helsinki Finland, Central Finland central hospital Jyväskylä Finland, Oulu university hospital Oulu Finland, Savonlinna central hospital Savonlinna Finland, Kanta-Häme central hospital Hämeenlinna Finland, Päijät-Häme central hospital Lahti Finland, Kainuu central hospital Kajaani Finland, Länsi-Pohja hospital Kemi Finland

Contact details

Study institution contact

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Primary lead investigator

Rafael Pasternack

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 14/11/2019

Study start date
Actual: 01/04/2020

Data analysis start date
Actual: 31/08/2020

Date of final study report
Actual: 18/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag Oy

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to investigate the real-life outcomes, and drug survival of guselkumab among patients with plaque psoriasis in Finland

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, non-interventional retrospective patient chart review study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

GUSELKUMAB

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

Finnish adult patients with confirmed diagnosis of plaque psoriasis (PSO) who have been initiated with guselkumab treatment between 1st December 2017 and 1st december 2019.

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

200

Study design details

Outcomes

The primary outcomes of the study regarding treatment outcomes are absolute psoriasis area and severity index (PASI) score, Body surface area (BSA) affected by plaque psoriasis, and Physician's global assessment. Regarding drug survival, primary outcome is treatment persistence. Secondary outcomes include guselkumab treatment patterns, guselkumab patient characteristics.

Data analysis plan

Descriptive methods will be used to summarize the outcomes. Differences in clinical outcomes will be tested with suitable statistical methods (e.g. student's t-test, Wilcoxon matched-pairs signed-rank test, test of proportions). Missing data points will be omitted from each corresponding analysis, data imputation techniques will not be considered in the base case analysis. However, this should not hinder the use of multivariate input methods, if needed and feasible given the sample size. The alpha level in the analyses is going to be set at 5%.

In the statistical procedures used hereby, results having a lower p-value than 0.050 will be considered statistically significant. In case of multiple comparisons, the familywise error will be set at 5%, thus lower than 0.050 significance level will apply to the single hypothesis testing.

Documents

Study, other information

FINGUS List of participating centres.pdf(81.99 KB)

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