

# 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

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### Study ID

39377

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### DARWIN EU® study

No

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### Study countries

 Finland

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### 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.

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## 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**

Rafael Pasternack studies@esior.fi

Study 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

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**Study start date**

Actual: 01/04/2020

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**Data analysis start date**

Actual: 31/08/2020

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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### **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

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### **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.

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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)
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## **Special population of interest**

Immunocompromised

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## **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.

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## **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

### 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)**

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No