

# The BRodalumab Assessment of Hazards: A Multinational Safety (BRAHMS) study in electronic healthcare databases

**First published:** 26/06/2019

**Last updated:** 16/12/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS30280

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### Study ID

43504


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### DARWIN EU® study

No

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### Study countries

 Denmark

 Germany

 Italy

 Netherlands

 Norway

 Sweden

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### University of Southern Denmark (SDU)

 Denmark


**First published:** 01/02/2024

**Last updated:** 27/03/2024

**Institution**

**Educational Institution**

#### Department of Epidemiology of the Regional Health Service - Lazio

 Italy

**First published:** 23/03/2010

**Last updated:** 22/06/2018

**Institution**

**Outdated**

**EU Institution/Body/Agency**

**ENCePP partner**

## Leibniz Institute for Prevention Research and Epidemiology - BIPS

 Germany

**First published:** 29/03/2010


**Last updated:** 30/03/2026

**Institution**

**Not-for-profit**

**ENCEPP partner**

## The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

 Netherlands

**First published:** 07/01/2022


**Last updated:** 19/12/2025

**Institution**

**Non-Pharmaceutical company**

**ENCEPP partner**

## Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

 Sweden

**First published:** 24/03/2010

**Last updated:** 23/04/2024

Institution


Educational Institution

Laboratory/Research/Testing facility

Not-for-profit

ENCePP partner

## Pharmacoepi center, University of Southern Denmark

 Denmark

**First published:** 22/04/2010


**Last updated:** 27/07/2023

Institution

Educational Institution

ENCePP partner

## Department of Chronic Diseases, Pharmacoepidemiologic Research Group, Norwegian Institute of Public Health (NIPH)

 Norway

**First published:** 29/04/2010

**Last updated:** 06/05/2024

Institution

Laboratory/Research/Testing facility

Other

ENCePP partner

## Universita di Verona, Department of Diagnostics and Public Health, Section of Pharmacology

# Contact details

## Study institution contact

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Study contact

[jhallas@health.sdu.dk](mailto:jhallas@health.sdu.dk)

## Primary lead investigator

Jesper Hallas

Primary lead investigator

# Study timelines

## Date when funding contract was signed

Actual: 17/04/2018

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## Study start date

Planned: 01/01/2020

Actual: 01/01/2020

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## Data analysis start date

Actual: 01/03/2024

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## Date of interim report, if expected

Planned: 07/06/2024

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## Date of final study report

Planned: 30/09/2030

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

LEO Pharma

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Data collection methods:**

Secondary use of data

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**Main study objective:**

The study aims to evaluate potential excess risks associated with the use of brodalumab in the treatment of psoriasis with regards to:

- 1) Suicidal attempts (fatal or non-fatal),
- 2) Serious infections (incident serious chronic infections or serious infections leading to hospitalization),
- 3) MACE (acute myocardial infarction, stroke or cardiovascular death),
- 4) Malignancies

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Case-crossover

## Study drug and medical condition

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

BRODALUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AC12) brodalumab

brodalumab

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**Medical condition to be studied**

Psoriasis

## Population studied

## **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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## **Estimated number of subjects**

50000

## **Study design details**

### **Outcomes**

- 1) Suicidal attempts (fatal or non-fatal),
  - 2) Serious infections (incident serious chronic infections or serious infections leading to hospitalization),
  - 3) MACE (acute myocardial infarction, stroke or cardiovascular death),
  - 4) Malignancies
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### **Data analysis plan**

Two different designs are used:

A case-time-control design is used in the analysis of 1) serious infections 2) suicidal behaviour and 3) MACE. In this design a patient's risk of experiencing an outcome while being exposed to brodalumab is compared to the same patient's risk of an outcome while not being exposed. Due to the inherently matched nature of the case-time-control design conditional logistic regression is used to calculate odds ratios.

An active-comparator cohort design is used in the analysis of 1) serious infections, 2) suicidal behaviour, 3) MACE, and 4) malignancies. In this design,

the event rate of outcomes among subjects exposed to brodalumab is compared to the event rate of outcomes among subjects who are exposed to other biological drugs. In the cohort design propensity score matching is used to adjust for confounding, whereas Cox proportional hazard model is used to calculate hazard ratios.

## Documents

### Study report

[NIS-KYNTHEUM-1345 Regulatory Agency - Progress Report\\_Redacted.pdf](#)

(711.16 KB)

[NIS-KYNTHEUM-1345 Regulatory Agency - Progress Report\\_Redacted 2020.pdf](#)

(224.96 KB)

### Study, other information

[NIS-KYNTHEUM-1345 Regulatory Agency - Progress Report\\_Redacted 2020.pdf](#)

(224.96 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.

This study has been awarded the ENCePP seal

## **Conflicts of interest of investigators**

[DoI forms\\_investigators.pdf](#) (2.7 MB)

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## **Composition of steering group and observers**

[Final vs 1.0\\_members\\_steering group.pdf](#) (64.69 KB)

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## **Signed code of conduct**

[2019-0062\\_Signed\\_Declaration on compliance with the ENCePP Code of Conduct.pdf](#) (324.29 KB)

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## **Signed code of conduct checklist**

[Vs 2.0\\_Signed\\_Checklist of ENCePP code of conduct.pdf](#) (313.59 KB)

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## **Signed checklist for study protocols**

[2019-0062\\_Signed\\_ENCePPChecklist for study protocols.pdf](#) (1.64 MB)

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# Data sources

## **Data source(s)**

Mortality Information System

Drug claims information system

Hospital Information System

Healthcare Emergency Information System

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Caserta claims database

PHARMO Data Network

German Pharmacoepidemiological Research Database

ARS Toscana

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**Data source(s), other**

NorPD

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**Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Other](#)

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**Data sources (types), other**

Exposure registry

## 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