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

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Administrative details

Contact details

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PURI

https://redirect.ema.europa.eu/resource/43504

EU PAS number

EUPAS30280

Study ID 43504

DARWIN EU® study

No

Study countries

Denmark

Germany

Italy

Netherlands

Norway

Sweden

Study status

Planned

Research institution and networks

Institutions

University of Southern Denmark (SDU) Denmark First published: 01/02/2024 Last updated 27/03/2024 Institution **Educational Institution**



Leibniz Institute for Prevention Research and **Epidemiology - BIPS**

Germany First published: 29/03/2010 Last updated 26/02/2024



Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina



The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands
First published: 07/01/2022
Last updated
Institution

Laboratory/Research/Testing facility

Netherlands
First published: 07/01/2022

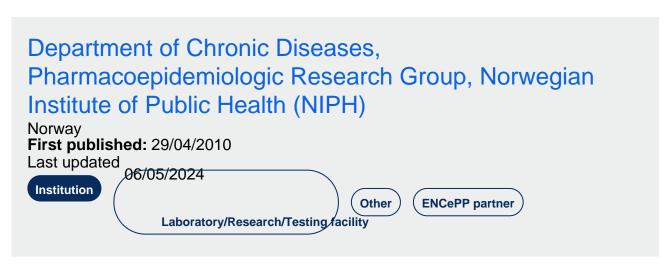
Last updated

Laboratory/Research/Testing facility



Pharmacoepi center, University of Southern Denmark





Study timelines

Date when funding contract was signed

Actual:

17/04/2018

Data collection

Planned: 01/01/2020

Date of final study report

Planned: 30/09/2030

Sources of funding

Pharmaceutical company and other private sector

More details on funding

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 list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

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 (acu

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Case-crossover

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

100000167238 brodalumab

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)

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

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

This study has been awarded the ENCePP seal



Conflicts of interest of investigators

Dol forms_investigators.pdf(2.7 MB)

Composition of steering group and observers

Final vs 1.0_members_steering group.pdf(64.69 KB)

Signed code of conduct

2019-0062_Signed_Declaration on compliance with the ENCePP Code of Conduct.pdf (324.29 KB)

Signed code of conduct checklist

Vs 2.0_Signed_Checklist of ENCePP code of conduct.pdf(313.59 KB)

Signed checklist for study protocols

2019-0062_Signed_ENCePPChecklist for study protocols.pdf(1.64 MB)

Data sources

Data source(s)

Mortality Information System

Drug claims information system Hospital Information System

Healthcare Emergency Information System

Danish registries (access/analysis)

National Prescribed Drugs Register / Läkemedelsregistret

Caserta claims database

PHARMO Data Network

German Pharmacoepidemiological Research Database

ARS Toscana

Data source(s), other

MIS, PHARM, HIS, HEIS, Danish Registries (access/analysis), The Swedish prescribed drug register, NorPD, Caserta database, PHARMO Data Network, GePaRD, ARS

Data sources (types)

Administrative data (e.g. claims)
Other

Data sources (types), other

Exposure registry

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