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

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

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 | EU Institution/Body/Agency | ENCePP partner

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution | Not-for-profit | ENCePP partner

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | 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

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Primary lead investigator

Jesper Hallas

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/04/2018

Study start date

Planned: 01/01/2020

Actual: 01/01/2020

Data analysis start date

Actual: 01/03/2024

Date of interim report, if expected

Planned: 07/06/2024

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

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

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

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

Non-interventional study design, other

Case-crossover

Study drug and medical condition

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

BRODALUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC12) brodalumab

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

DoI 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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Caserta claims database

PHARMO Data Network

German Pharmacoepidemiological Research Database

ARS Toscana

Data source(s), other

NorPD

Data sources (types)

Administrative healthcare records (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