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

First published: 26/06/2019
Last updated: 23/04/2024

Study | Planned

Administrative details

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Jesper Hallas
Primary lead investigator

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

Department of Epidemiology of the Regional Health Service - Lazio

Italy
First published: 23/03/2010
Last updated 22/06/2018

Institution

ENCePP partner

EU Institution/Body/Agency

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

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

Italy
First published: 29/11/2021
Last updated 01/12/2021

Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands
First published: 07/01/2022
Last updated 10/01/2022

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

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

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

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
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)
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