An Observational Post-Authorisation Safety Study of Lesinurad Patients (SATURATES)

First published: 05/07/2019

Last updated: 14/03/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44348

EU PAS number

EUPAS30385

Study ID

44348

DARWIN EU® study

No

Study countries

- ☐ Italy
- ☐ Spain
- ☐ United States

Study description

The study was withdrawn as Lesinurad was withdrawn from the market in Europe by the market authorization holder. Hence the commitment to do this PASS was removed by the European Medicines Agency. - Non-interventional population-based prospective cohort study in multiple databases comparing patients with gout who initiate lesinurad in combination with an existing xanthine oxidase inhibitor (XOI) (lesinurad+XOI cohort) to a propensity score-matched cohort of similar patients from the same data source who continue treatment with XOI monotherapy (XOI mono cohort). Study will characterize the cardiovascular safety of lesinurad in combination with XOI in patients with gout aged 18+ years compared with similar patients who continue XOI monotherapy. Primary objective: to assess the relative incidence of major adverse cardiac events plus hospitalization for unstable angina (MACE+ events) in patients with gout in both cohorts. Secondary objectives: to describe the characteristics of the cohorts prior to matching, to assess the relative incidence of hospitalisation for acute kidney injury between the matched cohorts, to assess the relative incidence of individual MACE+ components in the matched cohorts.

Study status

Planned

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain

- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Health Search, Italian College of General Practicioners

- [ ] Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | Educational Institution | Other

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

HealthCore United States

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elena Rivero

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/03/2016

Actual: 30/03/2016

Study start date

Planned: 30/09/2021

Data analysis start date

Planned: 30/11/2021

Date of final study report

Planned: 30/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astra Zeneca

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Other study registration identification numbers and links

D5310R00016

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:

To assess the relative incidence of major adverse cardiac events plus hospitalization for unstable angina (MACE+) events in patients with gout after lesinurad is added to their existing XOI therapy regimen and in patients continuing on XOI monotherapy.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional population based prospective cohort study

Study drug and medical condition

Name of medicine

ZURAMPIC

Anatomical Therapeutic Chemical (ATC) code

(M04AB05) lesinurad

lesinurad

Medical condition to be studied

Hyperuricaemia

Gout

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

131200

Study design details

Outcomes

Major Adverse Cardiac Events (MACE+), a composite endpoint comprised of: hospitalisation for non-fatal AMI, stroke, or unstable angina and cardiovascular (CV) death. CV death includes the following causes, occurring in or out of the hospital: AMI, sudden cardiac, heart failure, CV procedures, CV haemorrhage, stroke, underlying cerebrovascular cause, other CV causes. Hospitalisation for AKI including renal failure (with AKI as the primary diagnosis) and each individual component of MACE+.

Data analysis plan

Characteristics for both cohorts will be summarised at the index date. The primary effect estimate is the relative incidence and 95% CI of MACE+ during person-time exposed to lesinurad+XOI compared to that exposed to XOI mono. Time to event for the primary analysis is the day after the start of the index treatment until the first occurrence of a MACE+ or censoring event. Descriptive analyses of MACE+ events and person-time of follow-up will be stratified by patient age group and history of CV disorders. Analysis for secondary endpoints will be conducted analogously.Sensitivity analyses will evaluate the robustness of the estimate for the relative incidence of MACE+ between the two cohorts by differing assumptions for inclusion criteria, exposure definition, outcome definition, and potential unmeasured confounding.If feasible, separate pooled analyses of European data sources and US data sources may be performed.

Data management

Data sources

Data source(s)

Health Search/IQVIA Health Longitudinal Patient Database

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

HealthCore Integrated Research Database (HIRD) United States, Medicare United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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