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

First published: 05/07/2019

Last updated: 14/03/2024





Administrative details

| EU PAS number | |
|-------------------|--|
| EUPAS30385 | |
| Study ID | |
| 44348 | |
| DARWIN EU® study | |
| No | |
| Study countries | |
| Italy | |
| Spain 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The study was withdrawn as Lesinurad was withdrawn from the market in Europe by the market authorization holder.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 scorematched 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 (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 (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 | | | | | |
|--|---|---|--|--|--|--|--|
| 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 | 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 | United Kingdom (Northern Ireland) | | | | | |
| 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 | 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 | | | | | | |
| 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 | 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 | | | | | |
| 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 | 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 | Last updated: 13/03/2025 | | | | | |
| Practicioners Italy First published: 02/03/2010 Last updated: 20/08/2024 Institution | Practicioners Italy First published: 02/03/2010 Last updated: 20/08/2024 Institution | Institution Not-for-profit ENCePP partner | | | | | |
| Last updated: 20/08/2024 Institution Educational Institution Other RTI Health Solutions (RTI-HS) France Spain Sweden United Kingdom | 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 | Practicioners | | | | | |
| RTI Health Solutions (RTI-HS) France Spain Sweden United Kingdom | RTI Health Solutions (RTI-HS) France Spain Sweden United Kingdom United Kingdom (Northern Ireland) United States | First published: 02/03/2010 | | | | | |
| RTI Health Solutions (RTI-HS) France Spain Sweden United Kingdom | RTI Health Solutions (RTI-HS) France Spain Sweden United Kingdom United Kingdom (Northern Ireland) United States | Last updated: 20/08/2024 | | | | | |
| ☐ France☐ Spain☐ Sweden☐ United Kingdom | ☐ France ☐ Spain ☐ Sweden ☐ United Kingdom ☐ United Kingdom (Northern Ireland) ☐ United States | | | | | | |
| ☐ France☐ Spain☐ Sweden☐ United Kingdom | ☐ France ☐ Spain ☐ Sweden ☐ United Kingdom ☐ United Kingdom (Northern Ireland) ☐ United States | | | | | | |
| | | ☐ France ☐ Spain ☐ Sweden ☐ United Kingdom ☐ United Kingdom (Northern Ireland) ☐ United States | | | | | |
| | | | | | | | |

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: 23/05/2025

Institution Educational Institution (Laboratory/Research/Testing facility)

HealthCore United States

ENCePP partner

Contact details

Not-for-profit

Study institution contact

Elena Rivero ClinicalTrialTransparency@astrazeneca.com

Study contact

Clinical Trial Transparency @ astrazene ca.com

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

Medicinal product name

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

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.

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

| П | ln | V | n | \cap | ۱۸ | n |
|---|---|---|---|--------|----|---|
| u | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | ĸ | | () | vv | |

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No