Alert generation using the case-population approach in the French claims databases (ALCAPONE)

First published: 06/04/2016

Last updated: 24/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS13031

Study ID

49951

DARWIN EU® study

No

Study countries

☐ France

Study description

ALCAPONE aims to assess the suitability of the French nationwide healthcare insurance system database (SNIIRAM and EGB) for drug safety signal generation based on the OMOP reference set and methodologies, and the case-population approach. Once the initial calibration is completed, methods will be tested on incident alerts and suspected drugs.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicholas Moore

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/12/2014

Actual: 28/12/2014

Study start date

Planned: 02/10/2017

Actual: 02/10/2017

Data analysis start date

Planned: 01/11/2017

Date of interim report, if expected

Actual: 18/08/2017

Date of final study report

Planned: 31/12/2019

Actual: 31/10/2019

Sources of funding

- Other

More details on funding

Direction Générale de l’Offre de Soins (DGOS)

Study protocol

ALCAPONE-protocol-v1.1-20160405.pdf (1.42 MB)

ALCAPONE-protocol-v1.2-20160405.pdf (1.42 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If ‘other’, further details on the scope of the study

Pharmacovigilance signal generation

Data collection methods:

Secondary use of data

Main study objective:

The main objectives are:(i) To assess the performance of SNIIRAM for the detection of drug safety signals based on the OMOP reference set and methodologies(ii) To develop on SNIIRAM the case-population approach and assess its performance for safety signal generation based on the OMOP reference set.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-control study, Self-controlled case series, Case-population study

Study drug and medical condition

Medical condition to be studied

Acute myocardial infarction

Upper gastrointestinal haemorrhage

Acute kidney injury

Acute hepatic failure

Population studied

Short description of the study population

Patients with acute liver injury, myocardial infarction, kidney injury, and upper gastrointestinal bleeding identified from the French nationwide healthcare system claim databases SNIIRAM and EGB between 1 January 2009 and 31 December 2014.

Inclusion criteria:

- Patients presenting ALI, AKI, MI or UGIB between 01/01/2009 and 31/12/2014
- And having at least 182 days of healthcare history

Exclusion criteria:

- AKI: patients presenting previous renal transplantation or metal intoxication or specific kidney diseases
- ALI: patients presenting liver injury resulting from other causes than potential drug toxicity

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Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

66000000

Study design details

Outcomes

This study is based on the validation of the database according to the OMOP reference set (several series of molecules that have - positive controls - or have not - negative controls - been associated with four main events of interest). The identification of the true positive and the true negative drug-event pairs could be considered as the primary outcomes.

Data analysis plan

Three different designs are envisaged:(i) Case-control designOdds ratios (OR) will be calculated using a conditional logistic regression. Several degrees of matching will be considered, going from non-matched approach to disease risk score matching including loose matching on simply age and sex. (ii) Self-controlled case seriesRisk periods will be determined based on exposition and presumed biological mechanisms. Relative incidences (RI) for the risk periods will be computed.(iii) Case-population approachCase population ratio (CPR) will be calculated according to two distinct exposure approaches: a person-time approach and a per-user approach.The following evaluation criteria will be used to compare designs performanceThe receptor operating characteristics (ROC) will be used to choose the best compromise between sensitivity and specificity among the different designs and their variants according to drug-event pair characteristics.

Documents

Study results

ALCAPONE_Rapport_DGOSv1.0.pdf (380.85 KB)

Study publications

Thurin NH, Lassalle R, Schuemie M, Pénichon M, Gagne JJ, Rassen JA, Benichou J,...

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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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

ALCAPONE_Dol NMoore_2016.pdf (1.54 MB)

Composition of steering group and observers

ALCAPONE_steering group.pdf (90.11 KB)

Signed code of conduct

2016-0038-DoC CoC-SDPP-13031.pdf (330.04 KB)

Signed code of conduct checklist

2016-0038-Checklist CoC-SDPP-13031.pdf (1.12 MB)

Signed checklist for study protocols

2016-0038-Checklist Protocol-SDPP-13031.pdf (822.74 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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