Assessment of health complications associated with methadone use in the general population in France: incidence of hospitalizations and deaths and the role of drug-drug interactions (METHALICA)

First published: 12/07/2024

Last updated: 12/07/2024

Study Planned

Administrative details

EU PAS number

EUPAS1000000250

Study ID

1000000250

DARWIN EU® study

No

Study countries

France

Study status

Planned

Research institutions and networks

Institutions

Department of Clinical Pharmacology and Pharmacosurveillance, University Hospital of Marseille

France

First published: 12/12/2011

Last updated: 15/07/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Thomas Soeiro

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 03/11/2023

Study start date
Planned: 01/01/2024

Date of final study report
Planned: 31/12/2025

Sources of funding

- National competent authority (NCAs)

More details on funding

EPI-PHARE/ANSM

Study protocol

SOEIRO - projet METHALICA - document_scientifique_aap2023.pdf (981.56 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

METHADONE

Anatomical Therapeutic Chemical (ATC) code

(N02AC) Diphenylpropylamine derivatives

Diphenylpropylamine derivatives

(N07BC02) methadone

methadone

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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)

Système National des Données de Santé (French national health system main database)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes