Assessment of trajectories of high-risk drug users: incidence of abuse and impact on morbidity and mortality (METEOR)

First published: 12/07/2024

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Administrative details

PURI https://redirect.ema.europa.eu/resource/1000000248
EU PAS number
EUPAS100000248
Study ID
100000248
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

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse
France
First published: 31/03/2022
Last updated: 01/07/2024
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: 20/12/2021

Study start date

Planned: 01/01/2022

Date of final study report

Planned: 31/12/2024

Sources of funding

• National competent authority (NCAs)

More details on funding

EPI-PHARE/ANSM

Study protocol

MICALLEF projet METEOR - epi-phare document_scientifique_aap2021.pdf(1.13 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:

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

BUPRENORPHINE

FENTANYL

GABAPENTIN

METHADONE

MORPHINE

OXYCODONE

PREGABALIN

TRAMADOL

Anatomical Therapeutic Chemical (ATC) code

(N01AH01) fentanyl

fentanyl

(N02AA01) morphine

morphine

(N02AA05) oxycodone

oxycodone

(N02AB03) fentanyl

fentanyl

(N02AE01) buprenorphine

buprenorphine

(N02AX02) tramadol

tramadol

(N02BF01) gabapentin

gabapentin
(N02BF02) pregabalin
pregabalin
(N03AX12) gabapentin
gabapentin
(N03AX16) pregabalin
pregabalin
(N07BC01) buprenorphine
buprenorphine
(N07BC02) methadone
methadone

Data management

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

Yes			
Check compl	eteness		
Yes			
Check stabil	ity		
Yes			

Check logical consistency

Check conformance

Yes

Data characterisation

Data characterisation conducted

Yes