DARWIN EU® Use of take-home naloxone for opioid overdose treatment

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106379

EU PAS number

EUPAS105644

Study ID

106379

DARWIN EU® study

Yes

Study countries

- ☐ Belgium
- ☐ Germany
- ☐ Spain

United Kingdom

Study description

Opioid overdoses are the primary cause of mortality among problematic drug users globally. Naloxone, an opioid antagonist, can avert such fatalities by rapidly counteracting opioid effects. To address the frequent untreated overdoses due to the lack of recognition, fear of legal consequences, and lack of naloxone access, Take-Home Naloxone (THN) programs have been established, providing naloxone to potential bystanders in 12 European countries. This study will investigate the trend of naloxone use, particularly THN, across Europe, and elucidate user profiles to augment aggregated data from existing THN programs, thereby aiding the monitoring of naloxone use and informing regulatory decisions.

The objectives of this study are (i) To investigate the incidence and prevalence of THN use in (1) the general population and (2) among people with a recorded history of opioid use disorder during the study period 2017-2022. Analyses will be stratified by age, sex, calendar year and country/database. (ii) To provide summary baseline characteristics of “new” THN users including demographics, previous medical history, previous medication use and history of opioid use, overdose (iii) To study the use of THN in ”new” users including summary statistics of number of THN packages prescribed at index date for each “new” user (e.g. mean (SD), median, q25 and q75).

Study status

Finalised

Research institutions and networks

Institutions

Real-World-Evidence, IQVIA NL

Netherlands

First published: 25/11/2022

Last updated: 20/06/2024

Institution | Other | 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

Pharmaco- and Device epidemiology, University of Oxford

United Kingdom

First published: 12/09/2023

Last updated: 11/07/2024

Institution | Educational Institution | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom

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Network

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/05/2023

Actual: 04/05/2023

Study start date

Planned: 01/01/2017

Actual: 01/01/2017

Date of final study report

Planned: 01/11/2023

Actual: 16/11/2023

Sources of funding

- EMA

Study protocol

Study Protocol P2 C1-004 Version 2.1 final.pdf(1.63 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Study design:

- Population level cohort study
- New drug user cohort study

Main study objective:

(i) To investigate the incidence and prevalence of THN use in (1) the general population and (2) among people with a recorded history of opioid use disorder

during the study period 2017-2022.

(ii) To provide summary baseline characteristics of “new” THN users

(iii) To study the use of THN in ”new” users

Study drug and medical condition

Name of medicine, other

naloxone Nasal Spray

naloxone Prefilled Syringe

naloxone Auto-Injector

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

NALOXONE HYDROCHLORIDE DIHYDRATE

Anatomical Therapeutic Chemical (ATC) code

(V03AB15) naloxone

naloxone

Additional medical condition(s)

Opioid-induced mood disorder due to opioid abuse, Intravenous nondependent opioid abuse, Nondependent opioid abuse (continuous and episodic), Opioid abuse, Nondependent opioid abuse, Opioid-induced mood disorder due to opioid dependence, Opioid dependence with current use, Opioid analgesic dependence, Opioid dependence, Episodic opioid dependence, Continuous opioid dependence, Combined opioid with other drug dependence, Fentanyl dependence, Methadone dependence, Opium dependence, Heroin dependence, Morphine dependence

Population studied

Short description of the study population

Population-level utilization of THN: All individuals present in the database in the period between 01/01/2017 and 31/12/2022 will be included in the analysis after 365 days of database history. Therefore, children aged <1year will be excluded.

Patient-level THN utilization: All “new” users of THN in the period between 01/01/2017 and 31/12/2022, with “new” users being defined as all people with a prescription THN within the study period, with at least 365 days of availability prior to the date of their THN prescription and no prescription of THN in the last 7 days (180 days for sensitivity analysis). Therefore, the same person can be a “new” user multiple times during the study period.

Age groups

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

17700000

Study design details

Data analysis plan

Population-level THN use: Annual period prevalence of THN use and annual incidence rates per 100,000 person years in (1) the general population and (2) among people with a recorded history of opioid use disorder (OUD). Patient-level THN use: Summary baseline characteristics of “new” users incl. demographics and history of opioid use, overdose will be conducted. Index date will be the date of the respective prescription of THN for each person. Number of THN prescriptions/packages per “new” user at index date will be summarised and mean (SD), median, p25 and p75 provided. For all analyses a minimum cell count of 5 will be used when reporting results, with any smaller counts obscured.

Documents

Study report

DARWIN_EU_P2-C1-004_V2.1_forEUPAS.pdf(2.38 MB)

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Inpatient and outpatient specialist care

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No