

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

**First published:** 11/07/2023

**Last updated:** 11/07/2024

Study

Finalised

## Administrative details

### 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).

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[IQVIA NL, Real-World-Evidence](#)

Netherlands

**First published:** 25/11/2022

**Last updated:** 21/03/2025

**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:** 23/05/2025

**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
- Greece
- Hungary
- Italy
- Netherlands
- Norway
- Portugal
- Spain
- Sweden
- United Kingdom

**First published:** 01/02/2024

**Last updated:** 30/04/2025

**Network**

## Contact details

## **Study institution contact**

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[Study contact](#)

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## **Primary lead investigator**

Annika Jodicke

[Primary lead investigator](#)

## Study timelines

### **Date when funding contract was signed**

Planned: 04/05/2023

Actual: 04/05/2023

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### **Study start date**

Planned: 01/01/2017

Actual: 01/01/2017

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### **Date of final study report**

Planned: 01/11/2023

Actual: 16/11/2023

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## 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

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

Not applicable

## Methodological aspects

### Study type

#### Study type list

##### **Study type:**

Non-interventional study

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##### **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

### **Medicinal product name, other**

naloxone Nasal Spray  
naloxone Prefilled Syringe  
naloxone Auto-Injector

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

NALOXONE HYDROCHLORIDE DIHYDRATE

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### **Anatomical Therapeutic Chemical (ATC) code**

(V03AB15) naloxone  
naloxone

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### **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.

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## **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)

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## **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

### 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)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink

IQVIA Disease Analyzer Germany

IQVIA Longitudinal Patient Data - Belgium

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

Other

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### **Data sources (types), other**

Inpatient and outpatient specialist care

## Use of a Common Data Model (CDM)

### **CDM mapping**

Yes

### **CDM Mappings**

### **CDM name**

OMOP

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### **CDM website**

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

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## Data quality specifications

### **Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No