A multi-national, prospective mixed methods study of the effectiveness of naloxone (including intranasal Nyxoid) administration by lay people in reversing opioid overdose (NalPORS)

First published: 31/05/2021

Last updated: 02/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS41225

Study ID

45745

DARWIN EU® study

No

Study countries

Denmark

Sweden

United Kingdom (Northern Ireland)

Study status

Ongoing

Research institutions and networks

Institutions

King's College London

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

seunghee lee SeungHee.Lee@mundipharma.co.kr

Study contact

SeungHee.Lee@mundipharma.co.kr

Primary lead investigator

John Strang

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 12/02/2019

Actual: 12/02/2019

Study start date
Planned: 19/05/2021

Actual: 08/06/2021

Date of final study report
Planned: 31/08/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mundipharma Research Limited

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

1. To determine the frequency of deaths in the 24 hours or later if information is available subsequent to administration of naloxone by lay-persons to reverse an opioid overdose in the real world. 2. To determine the proportion of naloxone administration with the intention of reversing an opioid overdose by lay persons provided with THN who witness an opioid overdose.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Overdose

Additional medical condition(s)

Opioid Overdose

Population studied

Age groups

- 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

6.000

Study design details

Outcomes

1. frequency of deaths among those witnessing opioid overdose (n=600) 2. Rate of THN administration among those witnessing opioid overdose (n=600), .

Data analysis plan

The administration rate of THN by lay people and the frequency of deaths from the opioid overdose will be estimated as proportions. A Statistical Analysis Plan (SAP) will be developed throughout the study in conjunction with the co-sponsor standard operating procedures and will be approved by the Study Steering Committee (SSC) (see Section 10. Study oversight). The study data will be stratified by participants groups as follows: 1) Patients in treatment for OUD, 2) Participants who use opioids but are not currently in treatment, 3) Friends and family members, 4) Staff working with individuals with OUD. Effective administration rates of THN by lay people will be estimated in each sub-group, as proportions. The outcomes will also be estimated for each THN formulation.

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.

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