

# A multinational, observational study to investigate the use of dexmedetomidine (dexdor®) in clinical practice (DEXDUS)

**First published:** 18/12/2012

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS3243

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### Study ID

16725

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### DARWIN EU® study

No

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### Study countries

 Austria

 Finland

 Germany

 Poland

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## Study description

This is a multinational, observational, retrospective drug utilisation study. All patients, both adults and children, receiving Dexdor in participating sites will have pre-defined data elements collected retrospectively from the patient medical records. The data collected will be anonymised at the source.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Not ENCePP centre

Multiple centres: 16 centres are involved in the study

## Contact details

### Study institution contact

Mary Weatherall [mary.weatherall@orionpharma.com](mailto:mary.weatherall@orionpharma.com)

**Study contact**

[mary.weatherall@orionpharma.com](mailto:mary.weatherall@orionpharma.com)

### Primary lead investigator

Weatherall Mary

Primary lead investigator

## Study timelines

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

Planned: 01/09/2011

Actual: 01/09/2011

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### **Study start date**

Planned: 07/05/2013

Actual: 13/06/2013

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### **Data analysis start date**

Planned: 29/05/2015

Actual: 15/01/2015

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

Planned: 28/08/2015

Actual: 13/05/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Orion Pharma

# Study protocol

[3005021 Clinical study protocol synopsis.pdf](#) (161.15 KB)

[Synopsis of 3005021 2nd amended clinical study protocol.pdf](#) (162.96 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

#### Study type list

#### **Study topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To investigate the use of dexdor in clinical practice

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective observational study

## Population studied

**Short description of the study population**

All patients who were treated with Dexdor in participating sites.

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**Age groups**

- Preterm newborn infants (0 - 27 days)
- Term newborn infants (0 - 27 days)
- 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**

2000

## Study design details

### **Data analysis plan**

To evaluate the observed compliance with the current marketing license.

## 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.

### **Composition of steering group and observers**

[Membership of the Steering Committee and Orion representatives - version 1.0 7th June 2012.pdf](#) (67.03 KB)

[Membership of the Steering Committee and Orion representatives - Version 2.0 21st February 2013.pdf](#) (3.28 KB)

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## Data sources

## **Data sources (types)**

Other

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

Patient medical records

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## 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**

Unknown