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

First published: 18/12/2012

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Study Finalised

Administrative details

EU PAS number

EUPAS3243

Study ID

16725

DARWIN EU® study

No

Study countries

- Austria
- Finland
- Germany
- Poland

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 retrospectivelyfrom the patient medical records. The data collected will be anonymised at the source.

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

Study contact

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

Study start date
Planned: 07/05/2013

Actual: 13/06/2013

Data analysis start date
Planned: 29/05/2015

Actual: 15/01/2015

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

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To investigate the use of dexdor in clinical practice

Study Design

Non-interventional study design

Other

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.

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)

Estimated number of subjects

2.000

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)

Data sources

Data sources (types)

Other

Data sources (types), other

Patient medical records

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

Unknown