A retrospective, observational study to investigate the therapeutic value of dexmedetomidine (dexdor®) in clinical practice (DexBOS)

First published: 08/07/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS7037

Study ID

30353

DARWIN EU® study

No

Study countries

Belgium

Study description

This study will retrospectively collect data from medical records on the therapeutic use of patients who have been treated with dexdor since it's introduction to the study sites and compare this to control patients who did not receive dexdor.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres

Multiple centres: 2 centres are involved in the study

Contact details

Study institution contact

Sara Haworth sara.haworth@orionpharma.com

Study contact

sara.haworth@orionpharma.com

Primary lead investigator

Sara Haworth

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/06/2014

Actual: 09/07/2014

Study start date
Planned: 01/08/2014

Actual: 14/08/2014

Date of final study report
Planned: 02/05/2017

Actual: 15/02/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Orion Pharma

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Therapeutic use

Data collection methods:

Secondary use of data

Main study objective:

To investigate the therapeutic value of Dexdor in clinical practice in Belgium compared with matched control patients who received standard care.

Study Design

Non-interventional study design

Case-control

Population studied

Short description of the study population

Patients who have been treated with dexdor since it's introduction to the study sites.

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

200

Study design details

Data analysis plan

To investigate the therapeutic value of Dexdor compared with matched historical controls.

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 sources (types)

Other

Data sources (types), other

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