Leuprorelin and medication error and lack of effect - An analysis of EudraVigilance

First published: 21/01/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS39125

Study ID

39126

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

This was a descriptive study of case reports of medication errors and lack of efficacy reported to leuprorelin to EudraVigilance.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pinheiro Luis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/06/2019

Actual: 19/06/2019

Study start date
Planned: 19/06/2019

Actual: 19/06/2019

Data analysis start date
Planned: 19/06/2019

Actual: 19/06/2019

Date of final study report
Planned: 02/08/2019

Actual: 31/07/2019

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Case series review of Pharmacovigilance data

Data collection methods:

Secondary use of data

Main study objective:

The objective was to describe the characteristics of reports of medication errors and lack of effect to leuprorelin and potential consequences.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

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

LEUPRORELIN

Medical condition to be studied

Medication error

Additional medical condition(s)

Consequences of medication errors with leuprorelin

Population studied

Short description of the study population

The study focused on medication errors and lack of efficacy reports of leuprorelin-containing medicinal products identified from EudraVigilance database.

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

1707

Study design details

Data analysis plan

Descriptive statistics were performed to characterise the reports. These included an overview of case reports by population and drug characteristics, time-trend of case reports and distribution of reported reactions. Disproportionality statistics were calculated for at High level term (HLT) level. To perform the calculation at HLT level, all HLTs under the SMQs and SOCs as well as the HLT Reproductive hormone analyses were used.

Documents

Study results

Leuprorelin and ME and LE - EV report - 20190731.pdf(1.01 MB)

Data management

Data sources

Data source(s), other

EudraVigilance

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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