EMA study on prescribing of codeine to children and adolescents for cough and cold

First published: 17/02/2015

Last updated: 26/07/2016

Study Finalised

Administrative details

EU PAS number

EUPAS8639

Study ID

14397

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ United Kingdom

Study description

On 11 April 2014, the European Medicines Agency started a review of codeine-containing medicines when used for cough and cold in children. This follows a previous review of these medicines when used for pain relief in children, which was triggered by concerns over the risk of morphine toxicity. As a result of that review, several measures were introduced in order to minimise the risk of morphine toxicity when using codeine for pain relief. These included a recommendation that children with conditions associated with breathing problems should not use codeine. As the reasons for this recommendation may also apply to the use of codeine for cough and cold in children, an EU-wide review of such use has now been started.The present study is aimed at further determining the utilisation of codeine in real-life practice in the EU to treat cough and colds in children and adolescents.

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

Gianmario Candore gianmario.candore@ema.europa.eu

Study contact

gianmario.candore@ema.europa.eu

Primary lead investigator

Gianmario Candore

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/04/2014

Actual: 14/04/2014

Study start date

Planned: 15/04/2014

Actual: 15/04/2014

Data analysis start date

Planned: 30/04/2014

Actual: 30/04/2014

Date of final study report

Planned: 19/08/2014

Actual: 19/08/2014

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The present analyses primarily concern the utilisation of codeine in children. practice in Germany, general practice in France) will be performed. In addition, available on-line Nordic prescription registries will be queried. The study will also analyse the incidence of death occurring within a short time span of a codeine prescription.

Study drug and medical condition

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

CODEINE

Medical condition to be studied

Upper-airway cough syndrome

Population studied

Short description of the study population

Children and adolescents with cough and cold who have been prescribed Codeine.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Cough and cold patients

Estimated number of subjects

3700000

Study design details

Outcomes

The utilisation of codeine in children. practice in Germany, general practice in France) will be performed. The study will also analyse the incidence of death occurring within a short time span of a codeine prescription.

Data analysis plan

Descriptive drug utilisation study using the EMA’s in-house electronic health record (EHR) databases (IMS Germany, IMS France and THIN UK). In addition available on-line data on prescriptions dispensed from pharmacies in the three Nordic Countries have been used (Norway, Sweden and Denmark).

Documents

Study report

Codeine report EMA Cough & Cold Final.pdf(1.21 MB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

IMS United Kingdom

Data sources (types)

Electronic healthcare records (EHR)

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