

Prescribing of codeine for the treatment of pain in children. Drug utilisation study using IMS electronic health records in Germany and France.

First published: 04/01/2017

Last updated: 25/10/2022

Study

Finalised

Administrative details

EU PAS number

EUPAS17093

Study ID

49537

DARWIN EU® study

No

Study countries

France

Germany

Study description

In June 2013, the EU introduced risk minimisation measures (RMM) to the use of codeine for treatment of pain in children that included a contraindication in children below the age of 12 years, in children 0-18 years who undergo tonsillectomy or adenoidectomy (TA) for obstructive sleep apnoea, and in ultrarapid metabolisers of CYP2D6. Prescribers should use the lowest possible dose of codeine for the shortest possible time, and only prescribe codeine if other analgesics, e.g. ibuprofen or paracetamol, are insufficient. The aim of this study is to investigate the impact of RMM on prescribing of codeine for pain in children in the IMS France and Germany databases. Impact measures by age group (0-11 and 12-18 years) and gender include 3- or 6-monthly prevalences of codeine prescriptions, and before and after RMM the following measures: Prevalences by 1-year age groups, doses, durations, amounts, prescribing of analgesics before codeine, and prescribing of codeine in children undergoing TA.

Study status

Finalised

Research institutions and networks

Institutions

[European Medicines Agency \(EMA\)](#)

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Institution

Contact details

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/02/2015

Actual: 24/02/2015

Study start date

Planned: 10/11/2015

Actual: 10/11/2015

Data analysis start date

Planned: 11/11/2015

Actual: 11/11/2015

Date of final study report

Planned: 31/01/2017

Actual: 23/04/2019

Sources of funding

- EMA

Study protocol

[Drug utilization study of codeine for the treatment of pain in children.pdf](#)

(472.42 KB)

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 aim of this study is to investigate the impact of risk minimisation measures on prescribing of codeine for pain in children in the IMS France and Germany databases. Impact measures by age group (0-11 and 12-18 years) and gender include 3- or 6-monthly prevalences of codeine prescriptions, and before and after RMM the following measures: Prevalences by 1-year age groups, doses, durations...

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

CODEINE

Medical condition to be studied

Pain

Population studied

Short description of the study population

The study participants were children who has been prescribed codeine for the treatment of non-acute pain or pain in Germany and France.

Inclusion criteria:

- children below the age of 12 years
 - children between 12-18 years of age with non-acute pain or pain that is less than moderate in severity that can be relieved by other analgesics such as paracetamol or ibuprofen alone
 - children undergoing tonsillectomy, adenoidectomy or combined tonsillectomy/adenoidectomy for obstructive sleep apnoea
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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

Patients with non-acute pain

Estimated number of subjects

50000

Study design details

Outcomes

Prescribing of codeine in children before and after introduced risk minimisation measures.

Data analysis plan

Descriptive drug utilisation study using the EMA's in-house electronic health record (EHR) databases (IMS Germany, IMS France)

Documents

Study publications

[Hedenmalm K, Blake K, Donegan K, Macia MA, Gil M, Williams J, Montero D, Candor...](#)

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 source(s), other

IQVIA Disease Analyzer Germany, IMS LifeLink EMR France

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