Changes in alternative treatments for pain and cough in children after introduction of risk minimisation measures for codeine (Alternatives to codeine)

First published: 29/10/2019

Last updated: 30/01/2025

Study Finalised

Administrative details

EU PAS number

EUPAS32021

Study ID

44757

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Spain

United Kingdom

Study description

Europe-wide risk minimisation measures (RMMs) were introduced for the use of codeine for the treatment of pain relief in children in June 2013 to minimise the risk of serious adverse events. In April 2015, similar RMMs were also introduced for the use of codeine in the treatment of cough or cold in paediatric patients. This is a drug utilisation study in a cohort of patients under 18 years of age. The study has the following objectives: 1. To assess whether the codeine referrals for the treatment of pain and cough or cold in patients below 18 years of age were temporally associated with statistically significant changes in prescribing of alternative analgesics, antitussives or cold medicines in this patient population. 2. To describe prescribing trends for codeine and alternative analgesics and antitussives over time in patients below 18 years of age by evaluating the total number of children with a prescription and the total number of prescriptions of codeine and selected alternative analgesics and antitussives per time period: 2.1. In relation to all children in the database during the same time period. 2.2. Stratified by age group (0-11 years and 12-17 years) and gender.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

Spain

First published: 01/02/2024

Last updated: 04/09/2024

Institution | EU Institution/Body/Agency | Not-for-profit | Regulatory Authority | ENCePP partner

ANSM France, The Norwegian Medicines Agency Norway

Contact details

Study institution contact

Daniel Nogueras Zondag

danielantonio.nogueraszondag@ema.europa.eu

Study contact

danielantonio.nogueraszondag@ema.europa.eu

Primary lead investigator

Daniel Nogueras Zondag

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/01/2019

Actual: 01/01/2020

Study start date

Planned: 01/10/2019

Actual: 01/06/2020

Data analysis start date

Planned: 01/11/2019

Actual: 01/09/2020

Date of interim report, if expected

Actual: 31/01/2021

Date of final study report

Planned: 01/02/2019

Actual: 31/07/2021

Sources of funding

- EMA

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess whether the codeine referrals for the treatment of pain and cough or cold in patients below 18 years of age were temporally associated with statistically significant changes in prescribing of alternative analgesics, antitussives or cold medicines in this patient population.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

CODEINE

DEXTROMETHORPHAN

DIHYDROCODEINE

ETHYLMORPHINE

HYDROMORPHONE

METAMIZOLE

MORPHINE

OXYCODONE

PHOLCODINE

TRAMADOL

Population studied

Short description of the study population

The patient population consisted in all patients under the age of 18 years, with a particular focus on children below 12 eligible to be exposed to codeine or any of the alternative analgesics or antitussives of interest included in our study.

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)

Estimated number of subjects

750

Study design details

Data analysis plan

Interrupted time series analysis

Documents

Study results

Annex A - Tables and Figure.pdf(177.51 KB)

Annex B - Medicines use in children 12 to 18 years of age.pdf(747.48 KB)

Final Report.pdf(773.55 KB)

Data management

Data sources

Data source(s), other

NorPD, BIFAP

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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