Glucocorticoid-induced osteoporosis (GIOP): prescription patterns of glucocorticoids in paediatric patients

First published: 22/12/2021

Last updated: 01/03/2022

Study Finalised

Administrative details

EU PAS number

EUPAS44839

Study ID

46043

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany

Study description

This study looked at the prescription patterns of glucocorticoids in paediatric patients with a view to determine the long-term exposure to these medicinal products and the likelihood of this long-term exposure leading to glucocorticoid-induced osteoporosis.

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

Luis Pinheiro luis.pinheiro@ema.europa.eu

Study contact

luis.pinheiro@ema.europa.eu

Primary lead investigator

Luis Pinheiro

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 11/11/2021

Actual: 11/11/2021

Study start date
Planned: 11/11/2021

Actual: 11/11/2021

Date of final study report
Planned: 21/12/2021

Actual: 21/12/2021

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 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:

Can a sufficient number of paediatric patients exposed to long term prescription of glucocorticoid-containing products, and that develop fractures, be identified to suggest that recruitment for a clinical trial in GIOP is feasible?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H02A) CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

Medical condition to be studied

Osteoporotic fracture

Population studied

Short description of the study population

Patients with ages between 0 and 17 between 2015 and 2020 were included. All data from IMS FR and primary care data and paediatric speciality data from IMS DE were used.

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)

Estimated number of subjects

2500000

Study design details

Outcomes

Osteoporosis and/or fractures

Data analysis plan

A descriptive analysis of ten disorders likely to lead to long-term exposure to glucocorticoids was developed. Yearly prevalence of glucocorticoids was determined. Distribution of number of prescriptions of glucocorticoids per child was estimated. Incidence rates of osteoporosis and or fracture in patients

taking more than four prescriptions of glucocorticoids in a 180-day window were calculated.

Documents

Study results

Report - Prescription patterns of glucocorticoids in Paediatric patients.pdf (972.76 KB)

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)

Disease Analyzer - OMOP

IQVIA Disease Analyzer Germany

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