

# 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

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### Study ID

46043

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### DARWIN EU® study

No

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### Study countries

☐ France

☐ Germany

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## 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.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### European Medicines Agency (EMA)

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Luis Pinheiro [luis.pinheiro@ema.europa.eu](mailto:luis.pinheiro@ema.europa.eu)

Study contact

[luis.pinheiro@ema.europa.eu](mailto:luis.pinheiro@ema.europa.eu)

### Primary lead investigator

Luis Pinheiro

## Study timelines

### **Date when funding contract was signed**

Planned: 11/11/2021

Actual: 11/11/2021

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### **Study start date**

Planned: 11/11/2021

Actual: 11/11/2021

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### **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

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

Not applicable

## Methodological aspects

### Study type

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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

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## 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.

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### 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)

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### Estimated number of subjects

2500000

## Study design details

### Outcomes

Osteoporosis and/or fractures

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### 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)

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## Data management

### Data sources

#### Data source(s)

Disease Analyzer - OMOP

IQVIA Disease Analyzer Germany

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#### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No