Risk association of orofacial cleft and glucocorticoids exposure during pregnancy: a meta-analysis (GC_OC)

First published: 13/12/2018

Last updated: 05/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS26922

Study ID

33602

DARWIN EU® study

No

Study countries

Germany

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/07/2018

Actual: 02/07/2018

Study start date
Planned: 15/12/2018

Actual: 16/11/2018

Date of final study report
Planned: 28/02/2020

Actual: 28/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

20638_CSP_V1.2_2018-11-16_Redacted.pdf (779.96 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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To conduct a meta-analysis of published literature to investigate the association between the exposure of glucocorticoids during pregnancy and orofacial cleft development

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medicinal product name, other

Nerisona

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

DIFLUCORTOLONE VALERATE

Population studied

Short description of the study population

Pregnant women exposed to any glucocorticoid or corticosteroid or steroids in early pregnancy or first trimester of pregnancy irrespective of mode of administration.

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)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

99.999

Study design details

Outcomes

Incidence of any type of orofacial cleft, Potency of glucocorticosteroids, Route of administration of glucocorticosteroids

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Data analysis plan

In total 18 observational studies have been selected for this meta-analysis with sample size for individual studies ranging from 106 to 832,636 patients. Based on the evidence identified, risk association of orofacial cleft and glucocorticoids exposure during pregnancy will be assessed by the odds ratios (ORs) with corresponding 95% credibility intervals (CIs). Direct treatment comparison with any glicocorticoid vs. no use will be conducted. Fixed effect model will be used. Various sub-groups and sensitivity analyses will be performed.

Documents

Study results

20638_OS Report Abstract_redacted_for publication.pdf (243.33 KB)

Study report

20638_OS Report_B003036_redacted_for publication.pdf (635.33 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), other

Embase and Medline via Ovid®, Cochrane database, Google Scholar

Data sources (types)

Published literature

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