# 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**

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

**Study contact**

clinical-trials-contact@bayer.com

**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

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**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

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**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

**Name of medicine, 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.

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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)

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)

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**Special population of interest**

Pregnant women

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**Estimated number of subjects**

99999

## 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

## 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