# Retrospective Case-Control Studies of Rare Adverse Events Associated with Intranasal Steroids (201077)

**First published:** 21/04/2014

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS5049

**Study ID**

15565

**DARWIN EU® study**

No

**Study countries**

☐ United States

**Study description**

GSK Consumer Healthcare has funded an investigator-sponsored retrospective epidemiological study analyzing medical-pharmacy claims to determine odds ratios for developing glaucoma or cataract in relation totiming and duration of exposure to an intranasal steroid or intranasal fluticasone, and to determine the odds ratio for developing adrenal insufficiency after discontinuation of intranasal steroids or intranasal fluticasone.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### University of California

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

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**Institution**

# Contact details

**Study institution contact**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor cdr_mailbox@gsk.com

**Study contact**

cdr_mailbox@gsk.com

**Primary lead investigator**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 12/05/2012

Actual: 25/05/2012

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**Study start date**

Planned: 15/09/2012

Actual: 15/09/2012

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**Data analysis start date**

Planned: 15/09/2012

Actual: 15/09/2012

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**Date of final study report**

Planned: 30/05/2014

Actual: 23/05/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

# Study protocol

Case Study Redact_201077.pdf (214.77 KB)

# Regulatory

**Was the study required by a regulatory body?**

No

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

EU RMP category 3 (required)

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Disease /health condition

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

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**Main study objective:**

To determine risk ratios of corticosteroid treatment for case reports of cataracts and glaucoma associated with prescription intranasal corticosteroid use and to determine the odds ratios for developing adrenal insufficiency after discontinuation of intranasal steroids or intranasal fluticasone, with a focus on intranasal fluticasone use.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective Nested Case Controlled study

## Study drug and medical condition

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

FLUTICASONE FUROATE

FLUTICASONE PROPIONATE

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**Medical condition to be studied**

Glaucoma

Ocular hypertension

Cataract

Adrenal insufficiency

Glucocorticoid deficiency

# Population studied

**Short description of the study population**

Individuals continuously enrolled in the IMS database with both medical and pharmacy claims for at least 1 year in the IMS database.

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**Age groups**

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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**Estimated number of subjects**

0

# Study design details

**Outcomes**

The purpose of this research is to explore putative associations between exposure to intranasal steroids and the subsequent development of glaucoma, cataract or adrenal insufficiency

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**Data analysis plan**

The goals of this study will be to determine the odds ratios for developing glaucoma or cataract in relation to recent and length of exposure to intranasal steroid or intranasal fluticasone, and to determine the odds ratio for developing

adrenal Insufficiency after discontinuation of intranasal steroids or intranasal fluticasone.

## Documents

**Study results**

UCSFreport_NestedCC_INS_Glau-Cat-AI_MAY23-2014_ver1-4.pdf (367.9 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)**

THIN® (The Health Improvement Network®)

**Data sources (types)**

Other

**Data sources (types), other**

Case-control surveillance database

## 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**

Unknown