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

PURI

https://redirect.ema.europa.eu/resource/15565

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

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

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

Study start date

Planned: 15/09/2012

Actual: 15/09/2012

Data analysis start date

Planned: 15/09/2012

Actual: 15/09/2012

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

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

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

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.

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)

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

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

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