A cohort study on the association between acid-suppressing drugs in pregnancy and asthma in the offspring (Acid-suppressing Drugs Pregnancy Asthma Offspring)

First published: 08/03/2017

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17960

Study ID

18591

DARWIN EU® study

No

Study countries

Spain

Study description

In this observational cohort study (NCT01787435), women aged 18 to 45 years with completed pregnancies between January 1996 and December 2010 were identified from The Health Improvement Network, and were linked to infants. The relative risk of asthma in children who experienced prenatal exposure to PPIs and/or H2RAs were quantified, adjusting for potential confounders. Hazard ratios (HRs) were estimated using Cox proportional hazard models.

Study status

Finalised

Research institutions and networks

Institutions

Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

Spain

First published: 15/03/2010

Last updated: 15/02/2024

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Luis Alberto García Rodríguez
ClinicalTrialTransparency@astrazeneca.com

Study contact

ClinicalTrialTransparency@astrazeneca.com

Primary lead investigator

Luis Alberto García Rodríguez

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 13/12/2011

Study start date
Actual: 15/06/2013

Data analysis start date
Actual: 15/06/2014

Date of final study report
Actual: 15/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

D9612N00018_Redacted_protocol.pdf (390.03 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

D9612N00018

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 estimate the association between prenatal exposure of acid suppressing drugs and the risk of asthma during childhood.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A02BA) H2-receptor antagonists

H2-receptor antagonists

(A02BC) Proton pump inhibitors

Proton pump inhibitors

Population studied

Short description of the study population

All women aged 18–45 years and with at least one pregnancy between 1 January 1995 and 31 December 2010 identified from THIN database who have been enrolled with their PCP (Primary Care Physician) for at least 1 year and have had a health contact in the year prior to the last menstrual period (LMP) of the respective pregnancy.

Age groups

- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

10.116

Study design details

Outcomes

To estimate the association between prenatal exposure to proton pump inhibitors (PPIs) and the risk of asthma during childhood.To estimate the association between prenatal exposure to H2-receptor antagonists (H2RAs) and the risk of asthma during childhood.

Data analysis plan

Among the matched infant cohorts, Cox proportional hazard models were used to estimate the hazard ratio (HR) and 95% confidence intervals (CIs) of developing asthma associated with maternal prenatal exposure to acid-suppressing drugs. For PPIs and H2RAs, exposure was assessed at any time

during pregnancy and in each trimester of pregnancy. Different Cox regression models were used to adjust for various confounding factors.

Documents

Study publications

Cea Soriano L, Hernández-Díaz S, Johansson S, Nagy P, García-Rodríguez LA. Expo…

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)

Electronic healthcare records (EHR)

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