

# Asthma treatment in pregnancy and the frequency of adverse pregnancy outcomes (WEUSRTP4850)

**First published:** 19/07/2012

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS2628

### Study ID

9739

### DARWIN EU® study

No

### Study countries

☐ United Kingdom

## Study description

Fluticasone propionate (FP) is an inhaled corticosteroid (ICS) used for the treatment of asthma, often in combination with the long-acting  $\beta$ -agonist salmeterol. Owing to small numbers of pregnancy exposures in the past, little is known about the safety of FP when used during pregnancy. Now, however, there are sufficient 1st trimester exposed pregnancies on the General Practice Research Database to allow the overall risk of major congenital malformations (MCMs) following exposure to FP to be evaluated. This study aims to evaluate the safety profile of FP compared with exposure to all other ICS with all MCMs combined as the primary endpoint whilst taking into account potential confounders and exposure to other asthma medicines. Analyses will be carried out separately for FP alone and FP in combination. If appropriate the two groups will be combined. In order to give an overall picture of the risks of adverse pregnancy outcomes associated with asthma in general and different levels of asthma control, irrespective of the products used for treatment, this study will also evaluate - 1. The risk of MCMs in pregnancies to women with 'considerable to severe' and 'moderate' asthma activity during the 1st trimester of pregnancy compared with those with 'mild' asthma activity during the 1st trimester. 2. The prevalence of specific MCMs identified within the entire asthma population. 3. The risk of a spontaneous pregnancy loss to women with 'considerable to severe' and 'moderate' asthma activity during the 1st trimester of pregnancy compared with those with 'mild' asthma activity during the 1st trimester. 4. The risk of a pre-term delivery to women with 'considerable to severe' and 'moderate' asthma activity in the 3rd trimester of pregnancy compared with those with 'mild' asthma activity in the 3rd pregnancy trimester. 5. The analyses carried out for pre-term delivery will also be carried out to evaluate the risk of stillbirths and neonatal death.

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## Study status

Finalised

## Research institutions and networks

# Institutions

## University of Bath

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Institution

## Contact details

### Study institution contact

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Study contact

[r.a.charlton@bath.ac.uk](mailto:r.a.charlton@bath.ac.uk)

### Primary lead investigator

Corinne de Vries

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/06/2012

Actual: 01/06/2012

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### Study start date

Planned: 23/07/2012

Actual: 01/08/2012

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### **Date of final study report**

Planned: 28/02/2013

Actual: 31/07/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[Asthma in Pregnancy\\_University of Bath\\_ENCePP\\_July2012.pdf](#)(508.76 KB)

## Regulatory

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

No

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**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 evaluate the safety profile of fluticasone propionate compared with exposure to all other inhaled corticosteroids, with all major congenital malformations combined as the primary endpoint, whilst taking into account potential confounders and exposure to other asthma medicines. This will be carried out separately for FP alone and in combination. If appropriate the 2 groups will be combined.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(R03) DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

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**Medical condition to be studied**

Asthma

## Population studied

**Short description of the study population**

Females with asthma who had asthma related medical code recorded anytime before the pregnancy start date and at least one prescription for an asthma medicine in the 6 months before the pregnancy start date or during pregnancy and no asthma related Read medical code but at least 6 prescriptions for an asthma

medicine in their record before the pregnancy start date, including one in the 6 months before the pregnancy start date or during pregnancy.

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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)

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**Special population of interest**

Pregnant women

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## Estimated number of subjects

30000

## Study design details

### Outcomes

The primary outcome of interest will be all major congenital malformations (MCMs) combined. MCMs will be defined according to the EUROCAT (European network of population-based registers for the epidemiological surveillance of congenital anomalies) classification scheme. MCMs will exclude all chromosomal defects and congenital malformations known to be of a genetic origin. 1. Spontaneous pregnancy losses2. Pre-term births3. Stillbirths at >24 weeks gestation4. Neonatal deaths occurring in the first 4 weeks of life

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### Data analysis plan

The absolute risk of a pregnancy outcome with a major congenital malformation (MCM) will be calculated for the fluticasone propionate exposure groups, other inhaled corticosteroid (ICS) exposure group and the entire asthma cohort stratified by asthma activity level. The relative risk of an MCM following first trimester exposure to fluticasone propionate compared to all other ICS will be calculated stratified by asthma activity level during the 1st trimester. The prevalence of different types of MCMs identified in the fluticasone propionate exposure groups, other ICS exposure group and the entire asthma cohort will be calculated. The risk of a spontaneous pregnancy loss, a pre-term delivery and a stillbirth will be calculated separately for the entire asthma cohort stratified by asthma activity level. Comparisons will be made between women classed as having 'considerable to severe' asthma activity and 'moderate' asthma activity to those with 'mild' asthma activity.

## Documents

## Study results

[EUPAS2628-9187.pdf](#)(273.33 KB)

[WEUSRTP4850\\_Clinical Study Result Summary.pdf](#)(67.1 KB)

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## Data management

### ENCePP Seal

This study has been awarded the ENCePP seal



### Conflicts of interest of investigators

[2012-0011-Dol C de Vries\\_SDPP-2628.pdf](#)(189.59 KB)

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### Composition of steering group and observers

[EUPAS2628-2818.pdf](#)(162.77 KB)

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### Signed code of conduct

[2012-0011-DoC-CoC\\_SDPP-2628.pdf](#)(29.39 KB)

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### Signed code of conduct checklist

[2012-0011-Checklist CoC\\_SDPP-2628.pdf](#)(364.59 KB)

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### Signed checklist for study protocols

[2012-0011-Checklist Protocol\\_SDPP-2628.pdf](#)(155.27 KB)

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## Data sources



**Data source(s)**

Clinical Practice Research Datalink

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**Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No