

# Exogenous sex steroid hormones and asthma in females: a population-based retrospective cohort study using primary care data

**First published:** 06/03/2018

**Last updated:** 21/02/2024

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/22968>

### EU PAS number

EUPAS22967

### Study ID

22968

### DARWIN EU® study

No

### Study countries

United Kingdom

### Study description

**Introduction:**Female sex steroid hormones have been implicated in sex-related differences in the development and clinical outcomes of asthma. The role of exogenous sex steroids however remains unclear. We aim to investigate whether the use of hormonal contraception and hormone replacement therapy (HRT), subtypes, and route of administration are associated with asthma onset and clinical outcomes in reproductive age and peri-menopausal/post-menopausal females. **Methods and analysis:** Using the Optimum Patient Care Research Database (OPCRD), a national primary care database in the UK, we will construct a retrospective longitudinal cohort of reproductive age (16-45

years) and peri-menopausal/post-menopausal (46+ 70years) females. We will estimate the risk of new-onset asthma using Cox regression and multilevel modelling for repeated asthma outcomes, such as asthma attacks. We will adjust for confounding factors in all analyses. We will evaluate interactions between the use of exogenous sex hormones and body mass index and smoking by calculating the relative excess risk due to interaction and the attributable proportion due to interaction. With 90% power, we need 23,700 reproductive age females to detect a 20% reduction (risk ratio 0.8) in asthma attacks for use of any hormonal contraception and 6,000 peri-menopausal/post-menopausal females to detect a 40% (risk ratio 1.40) increased risk of asthma attacks for use of any HRT. Conclusions: This study aims to overcome the limitations of previous studies, thereby providing the most robust evidence to help gain better insights into the effect of sex steroid hormones in the pathogenesis and clinical outcomes of asthma in females. We will present our findings at national and international scientific meetings and

## Study status

Ongoing

## Research institution and networks

### Institutions

**University of Edinburgh**  
United Kingdom  
**First published:** 23/11/2018  
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**Institution**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

**ENCePP partner**

## Contact details

### Study institution contact

Bright Nwaru

Study contact

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### Primary lead investigator

Bright Nwaru

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual:

02/01/2017

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**Study start date**

Actual:

02/10/2017

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**Date of final study report**

Planned:

31/12/2018

## Sources of funding

- Non for-profit organisation (e.g. charity)

## More details on funding

Asthma UK

## Study protocol

[Exogenous Sex Hormones and Asthma in Females OPCR Protocol.pdf](#)(219.79 KB)

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

To investigate the role of exogenous sex steroid hormones in the development of asthma and manifestation of clinical and patient-reported outcomes in females

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Asthma

## Population studied

**Age groups**

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**

25000

## Study design details

**Outcomes**

New-onset asthma, asthma attacks and severity, patient-reported asthma symptoms, medication use and health-related quality of life

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**Data analysis plan**

We will use Cox proportional hazards regression to study the associations between exogenous sex hormones and the first record of an asthma event. Multilevel modelling will

be used to estimate associations where the outcomes are repeated, e.g. number of asthma attacks and medication use. Since the change in hormone levels with contraceptive use is expected to differ between women, random coefficient models will be fitted, so that in turn the relationship between contraception use and asthma outcomes can differ between women. We will undertake analyses incorporating propensity scores using matching (exposed vs. unexposed).

## Data management

### Data sources

**Data source(s)**

Optimum Patient Care Research Database

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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