

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

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Study

Ongoing

Administrative details

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 institutions and networks

Institutions

University of Edinburgh (UofE)

☐ United Kingdom

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Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

Contact details

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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

Study start date

Actual: 02/10/2017

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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)

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

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

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

No