Pregnancy protection and pregnancies in women of reproductive age on ACE-Inhibitors (ACEi), Angiotensin Receptor Blockers (ARB), statins or anti-diabetic medications: an observational study in primary care.

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Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS106500

Study ID

106501

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Background The number of people living with long-term conditions, such as high blood pressure, high cholesterol, and diabetes, is on the rise. This includes women of reproductive or childbearing age. Increasing numbers of women in this group are prescribed medicines by their GPs to treat these conditions. Some of these medicines, if taken during pregnancy, have the potential to harm an unborn baby. Our earlier published work focussed on medications for high blood pressure, called angiontensin-converting enzyme inhibitors (ACEis) and angiotensin receptor blockers (ARBs). We estimated that over half of women are not told about the risks of these medications and not told to use effective contraception. To our knowledge, this research has not been expanded to look at a wider range of other potentially harmful medicines, to understand how big this problem is. We plan to find out: How often are medications for high blood pressure, high cholesterol and diabetes are prescribed to women of childbearing age? How many of these women have a pregnancy? How often are this group prescribed effective contraception? Methods We will answer these questions by using the Clinical Practice Research Datalink (CPRD) which collects anonymised patient data from UK GP practices. This includes 60 million patient records. We will look the medical records of a sample of women aged 15-49 from this database to answer our questions. We will use our results to understand how large this problem is in UK primary care and try to find out whether current practice is putting women and their babies at potential risk. We will inform patient groups, GPs and appropriate regulatory bodies about our results, to ensure any improvements needed can be made long term. The knowledge gained will form essential preliminary work towards future research, to help women to make better decisions about their treatments and pregnancy plans and improve care and prescribing in this area.

Study status

Planned

Research institutions and networks

Institutions

University of Southampton

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elizabeth Lovegrove

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/03/2023

Study start date
Planned: 01/11/2023

Date of final study report
Planned: 01/07/2024

Sources of funding

- Other

More details on funding

NIHR School for Primary Care Research

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:

Drug utilisation

Main study objective:

The overall objective is to ascertain how many women of reproductive age (15-55 years) are prescribed potentially teratogenic, but commonly prescribed, medications including ACEi and ARBs, anti-diabetic medications (excluding metformin and insulin) and statins. Then to evaluate what proportion of these women are prescribed contraception or have a pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C10AA01) simvastatin

simvastatin

(A10BK01) dapagliflozin

dapagliflozin

(C09AA05) ramipril

ramipril

(C09CA06) candesartan

candesartan

Medical condition to be studied

Pregnancy

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

12500

Study design details

Outcomes

1. Proportion of patients with the exposure who had a coded prescription for contraception up to 10 years prior to initiation of the medication of interest 2. Proportion of patients with the exposure who had a pregnancy coded in the pregnancy registry whilst in receipt of an active prescription of a medication of interest

Data analysis plan

Patient characteristics, rates of prescription for medications of interest, proportion of patients receiving a contraception prescription and/or conceiving

a pregnancy will be summarised using descriptive statistics, using counts/percentages or means/medians as appropriate for categorical and continuous variables, respectively. Data will be reported as per STROBE and RECORD guidelines for observational studies using routinely collected health data, analysed using STATA and described graphically where appropriate.

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 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