Exposure to ACEi, ARB and statin drugs among women of child-bearing age in Denmark

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Study Ongoing

Administrative details

EU PAS number

EUPAS106995

Study ID

106996

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

Cardiometabolic disorders are common. Increasing prevalence among younger people of hypertension, type 2 diabetes and hyperlipidaemia has seen rising numbers of women of child-bearing age prescribed drugs that modulate the renin-angiotensin system (RAS) or that lower cholesterol levels. Among RAS-acting drugs, both angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) are known teratogens when foetal exposure occurs in the second or third trimester. There is debate as to the teratogenicity risk associated with first trimester exposure. Statins, hydroxy methyl glutaryl Co-A (HMG-Co A) reductase enzyme inhibitors, are considered possibly teratogenic but epidemiological studies to date have not described convincing associations with foetal harm. In Denmark, ACEI and ARB have a ‘Do not use’ recommendation in pregnancy. A caveat with ACEIs is that first trimester teratogenic risk is interpreted as similar to the risk from hypertension itself (e.g., ramipril SPC) while second and third trimester exposure is considered teratogenic. Statins have a ‘should not be used’ in pregnancy recommendation owing to insufficient data on their effects. Despite their teratogenicity, studies in the UK and the US have reported that pregnancies have occurred among women prescribed ACEI and ARB drugs as well as prescription without concomitant contraception and/or without a record of having been advised about teratogenic risk. There are similar reports from European countries, Australia and Taiwan. To the best of our knowledge, no studies have investigated the situation in Denmark. This study examines prescribing of RAS-acting drugs and statins among women of child-bearing age in Denmark. It compares prescribing of the drugs among women of child-bearing age with that among men of similar ages.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patricia McGettigan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/01/2023

Actual: 06/01/2023

Study start date

Planned: 15/06/2023

Actual: 15/06/2023

Date of final study report

Planned: 18/09/2024

Sources of funding

- Other

More details on funding

Danish Cardiovascular Academy

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To examine prescribing of RAS-acting drugs and statins among women of child-bearing age in Denmark

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C09C) ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

(C10AA) HMG CoA reductase inhibitors

HMG CoA reductase inhibitors

(C09A) ACE INHIBITORS, PLAIN

ACE INHIBITORS, PLAIN

Population studied

Short description of the study population

National population

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

90000

Study design details

Outcomes

ACEi, ARB and statin prescribing to women of child-bearing age, categorized in age-bands, 1997-2021 compared with prescribing to age-matched men; first-time prescriptions; continuity of prescriptions after initiation; ceasing; switching • Concomitant prescription of contraception among women of child-bearing age

Data analysis plan

Descriptive statistics; Comparative prescription / switching / cessation across age groups and sex; Data to be reported as per STROBE and RECORD guidelines for observational studies using routinely collected health data

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)

Danish registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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