Statins and the risk of adrenal insufficiency: a nested case-control study (R.USTESE)

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Study   Ongoing

Administrative details

EU PAS number

EUPAS48277

Study ID

48278

DARWIN EU® study

No

Study countries

France

Study description

By inhibiting cholesterol synthesis, statins could reduce the synthesis of steroid hormones, thus causing adrenal insufficiency. We conducted a nested case-control study using the Système National des Données de Santé. The source

population was patients ≥18 years of age, affiliated to the General Health Insurance Scheme in 2010 with no history of adrenal insufficiency. Cases were patients presenting with a first adrenal insufficiency event between 01/01/2015 and 31/12/2017. Adrenal insufficiency was defined as the presence of both a hospital stay with a diagnosis of adrenal insufficiency (ICD-10 codes E271 to E274), and a first delivery of hydrocortisone ±30 days before/after hospital admission. Each case was matched to up to 10 controls on age (±2 years), sex and corticosteroid exposure in the 3 years prior to the index date. Statin exposure was measured in the 5 years prior to the index date using different definitions: history of use, cumulative use and intensity of last statin used. A 6-month censoring period for exposure was applied before the index date to avoid potential detection bias. The association was estimated using conditional logistic regression adjusted for confounders included in a disease risk score. Analyses were stratified on age, sex and history of corticosteroid use.

Study status

Ongoing

Research institutions and networks

Institutions

Academic Center for Pharmacoepidemiology (DRUGS-SAFEr)

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Institution

Contact details

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Primary lead investigator

Julien Bezin

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Study timelines

Date when funding contract was signed

Actual: 07/11/2019

Study start date

Actual: 20/12/2019

Date of final study report

Planned: 30/06/2022

Sources of funding

- Other

More details on funding

ANSM

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

Main study objective:

to assess the association between statin exposure and the development of adrenal insufficiency.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C10AA) HMG CoA reductase inhibitors

HMG CoA reductase inhibitors

Medical condition to be studied

Adrenal insufficiency

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

50000

Study design details

Outcomes

Adrenal insufficiency

Data analysis plan

The association will be estimated using conditional logistic regression adjusted for confounders included in a disease risk score. Analyses will be stratified on age, sex and history of corticosteroid use.

Data management

ENCePP Seal

Data sources

Data source(s), other

SNDS France

Data sources (types)

Administrative healthcare records (e.g., claims)

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