Use of Low-dose Quetiapine and the Risk of Major Adverse Cardiovascular Events

First published: 18/01/2021

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Study Planned

Administrative details

EU PAS number

EUPAS38508

Study ID

43842

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

Quetiapine is frequently used off-label in low-doses for its anxiolytic-hypnotic properties. Quetiapine has been associated with both metabolic disturbances and cardiac arrhythmias, when used in high doses for treatment of severe

mental illness, but it is not known whether the use of low doses is associated with an increased risk of major adverse cardiovascular events (MACE). The study is a new-user, active-comparator cohort study which aims to assess the association between the use of low-dose quetiapine and the risk of MACE using Danish health registers.

Study status

Planned

Research institutions and networks

Institutions

University of Southern Denmark (SDU)

Denmark

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Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Mikkel Højlund

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/11/2018

Study start date
Planned: 01/12/2020

Data analysis start date
Planned: 18/01/2021

Actual: 01/06/2021

Date of final study report
Planned: 01/10/2021

Sources of funding

- Other

More details on funding

Psychiatric Research Fund Region of Southern Denmark

Study protocol

Quetiapine_CVD_protocol_180121.pdf (146.1 KB)

quetiapine_cvd_protocol_27oct21.pdf (193.21 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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To investigate the association between the use of low-dose quetiapine and major adverse cardiovascular events.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05AH04) quetiapine

quetiapine

(N05CF) Benzodiazepine related drugs

Benzodiazepine related drugs

Medical condition to be studied

Cardiac death

Acute myocardial infarction

Ischaemic stroke

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

850000

Study design details

Outcomes

Primary outcome is major adverse cardiovascular events defined as a composite of: i) Death from cardiovascular causes, ii) non-fatal myocardial infarction, or iii) non-fatal stroke. Secondary outcomes are the individual items of the primary (composite) outcome: i) Death from cardiovascular causes, ii) non-fatal myocardial infarction iii) non-fatal stroke.

Data analysis plan

Intention-to-treat-like and on-treatment-like analyses will be conducted on the full cohort using propensity-score weighting to adjust for baseline confounding. The main measure of risk is hazard ratios. Furthermore, we will calculate the number of cases attributable to use of low-dose quetiapine.

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 source(s), other

Danish Registries (access/analysis)

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