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

PURI
https://redirect.ema.europa.eu/resource/43842

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 institution and networks

Institutions

University of Southern Denmark (SDU)

Denmark
First published: 01/02/2024
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27/03/2024
Institution
Educational Institution

Contact details

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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
(N05CF) 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

Data sources

Data source(s)
Danish registries (access/analysis)

Data source(s), other
Danish Registries (access/analysis)

Data sources (types)
Administrative data (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