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

**First published:** 18/01/2021

**Last updated:** 22/02/2024





### 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
First published: 01/02/2024
Last updated: 27/03/2024
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)

## 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