RRA-17401, Risperidone Exposure and the Risk of Osteoporosis-related Fractures – Taiwan

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Study Finalised

Administrative details

EU PAS number

EUPAS20730

Study ID

24441

DARWIN EU® study

No

Study countries

Taiwan

Study status

Finalised

Research institutions and networks

Institutions

Kaohsiung Municipal Kai-Syuan Psychiatric Hospital

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Darmendra Ramcharran

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/04/2015

Study start date

Actual: 01/06/2015

Date of final study report

Actual: 21/02/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Research & Development (JRD)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To compare the exposure of risperidone and other atypical antipsychotics in association with hip/femur fracture incidence. To estimate and compare the incidence of hip/femur fractures in users of risperidone, user of other atypical antipsychotics, and users of conventional antipsychotics.

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

RISPERIDONE

Medical condition to be studied

Hip fracture

Population studied

Short description of the study population

Adult patients with hip fracture with or without exposure to risperidone.

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)

Special population of interest

Other

Special population of interest, other

Hip fracture patients

Estimated number of subjects

748.729

Study design details

Outcomes

Hip and femur fractures, Non-hip and femur fractures

Data analysis plan

Incidence rates of osteoporosis-related fractures were estimated for each of the three cohorts, according to total cohort follow-up time and active treatment follow-up time, respectively, and reported as number of cases per 100,000 person-years. Hazard ratios (HRs) and 95% confidence intervals (CIs) for osteoporosis-related fractures among those exposed to risperidone compared with those exposed to other atypical antipsychotics or typical antipsychotics

were estimated. Odds ratio (OR) and 95% CI for osteoporosis-related fractures was estimated by comparing exposure to risperidone to exposure to other atypical antipsychotics, among cases and controls. The exposures were studied retrospectively from the date of diagnosis of an osteoporosis-related fracture in the following time categories: any time, current, recent, and past.

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 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

Unknown