RRA-17425, Risperidone Exposure and the Risk of Osteoporosis-related Fractures – Sweden

First published: 02/08/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/24438

EU PAS number

EUPAS20197

Study ID

24438

DARWIN EU® study

No

Study countries

☐ Sweden

Study status

Finalised

Research institutions and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Darmendra Ramcharran

Study contact

dramchar@its.jnj.com

Primary lead investigator

Darmendra Ramcharran

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/02/2016

Study start date
Planned: 19/02/2016

Actual: 19/02/2016

Date of final study report
Actual: 15/09/2017

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, users 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

116347

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 threecohorts, 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 bycomparing exposure to risperidone to exposure to other atypical antipsychotics, amongcases 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

Data sources

Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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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