# 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

**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 dramchar@its.jnj.com

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

## 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)**

Sweden National Prescribed Drugs Register / Läkemedelsregistret

**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