RRA-12037, Risperidone breast cancer study - Sweden

First published: 13/10/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS20733

Study ID

23219

DARWIN EU® study

No

Study countries

Sweden

Study status

Finalised

Research institutions and networks

Institutions

N/A

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: 10/02/2016

Study start date

Actual: 04/06/2013

Date of final study report

Actual: 31/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen R&D

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 anti-psychotics in association with breast cancer incidence. To estimate and compare the incidence of breast cancer 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

Anatomical Therapeutic Chemical (ATC) code

(N05AX08) risperidone

risperidone

Medical condition to be studied

Breast cancer female

Population studied

Short description of the study population

Adult females with breast cancer who were treated with 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

Breast cancer patients

Estimated number of subjects

55976

Study design details

Outcomes

Case Control Study: Estimation of the odds ratios (ORs) of breast cancer comparing exposure to risperidone with exposure to OAA among cases and controls. Estimation of the ORs of breast cancer, for each cancer stage, comparing exposure to risperidone with exposure to OAA among cases and controls.

Data analysis plan

To compare the exposure of risperidone and other atypical antipsychotics in association with breast cancer incidence. To estimate and compare the incidence of breast cancer in users of risperidone, users of other atypical antipsychotics, and users of conventional antipsychotics.

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