The Risk of Esophageal Cancer in Relation to the Treatment and Prevention of Osteoporosis in Women (MK-0217A-352)

First published: 19/04/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS17909

Study ID

19310

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This is a 2-phase retrospective database study, using both case-cohort and inception (intention-to-treat) cohort analyses to evaluate any association between oral treatments for osteoporosis and the risk of esophageal cancer in women.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.
datasharing@organon.com

Study contact

datasharing@organon.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/07/2009

Study start date
Actual: 26/02/2010

Data analysis start date
Actual: 16/02/2012

Date of final study report
Actual: 31/03/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

0217A-352 protocol_final-redaction.pdf(770.06 KB)

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)

Other study registration identification numbers and links

MK-0217A-352NCT01077817

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 quantify the relation between prescription of agents used in the treatment of osteoporosis and the subsequent occurrence of esophageal cancer.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-cohort

Study drug and medical condition

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

ALENDRONATE SODIUM

ETIDRONATE DISODIUM

RALOXIFENE

RISEDRONATE SODIUM

SODIUM IBANDRONATE

Medical condition to be studied

Gastrooesophageal cancer

Squamous cell carcinoma

Adenocarcinoma

Population studied

Short description of the study population

Women born between 1922 and 1953 with records in the GPRD between 1996 and 2008 who begins treatment for osteoporosis.

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

684815

Study design details

Outcomes

1. Percentage of Participants With Exposure to Study Drugs (Case-Cohort Analysis) 2.Number of Cases of Esophageal Cancer Per 100,000 Woman-Years (Intent-to-Treat Analysis)

Data analysis plan

In the case-cohort study, the effects of covariates and drug exposures were evaluated through a logistic regression model with conditioning on the matched set consisting of the case and her controls. In the intent-to-treat analysis, a proportional hazards regression model was used, with stratification on year of birth, calendar quarter of cohort entry, and exposure history. Both analyses used a robust variance estimator to account for the participation of individuals in multiple matched sets or strata.

Documents

Study results

0217A-352 Final Report_final-redaction.pdf(287.63 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Sources of data were female participants with esophageal cancer (cases) and a comparison subcohort in a case-cohort analysis performed using women meeting criteria from the General Practice Research Database (United Kingdom).

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