Estudio de casos y controles sobre el riesgo de fractura atípica de fémur asociada al uso de bifosfonatos

First published: 28/01/2015

Last updated: 13/12/2018

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26997

EU PAS number

EUPAS8463

Study ID

26997

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Objectives: to evaluate the association between bisphosphonate use and the risk of atypical femoral fractures among women aged 50 or older. Desing: case-control study. Main outcome measures: Cases were defined as women aged 50 years or older with diagnosis of subtrochanteric or diaphyseal fracture, recorded in the Data Warehouse Southern Metropolitan Management Administration Area of the ICS between 1 April 2010 and 31 December 2014, and with at least 1 year of follow-up before the index date. Four each case, for age-matched and primary healthcare facility-matched controls were selected from the database. Statistical analysis: OR for atypical femoral fracture risk associated to the use of bisphosphonates will be determined by logistic regression. Model will be adjusted for comorbidities and use of other drugs.

Study status

Ongoing

Research institutions and networks

Institutions

Bellvitge University Hospital

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Institution

IDIBELL

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/01/2015

Study start date

Planned: 02/03/2015

Actual: 02/03/2015

Data analysis start date

Planned: 01/01/2019

Date of final study report

Planned: 31/12/2019

Sources of funding

- Other

More details on funding

No specific funding

Study protocol

Protocolo T13 VAL-SI V1 27-01-15.pdf(129.13 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The aim of this study is to evaluate the association between the use of bisphosphonates and the risk of subtrochanteric or diaphyseal fractures among women aged 50 or older.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M05BA) Bisphosphonates

Bisphosphonates

(M05BB) Bisphosphonates, combinations

Bisphosphonates, combinations

Medical condition to be studied

Atypical femur fracture

Population studied

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

380

Study design details

Outcomes

Evaluate the association between the use of bisphosphonates and the risk of subtrochanteric or diaphyseal fractures among women aged 50 or older, Hospitalization data, demographics data, anthropometrics data, toxic habits data, clinical data, prescribed medication data, complementary examinations data, body mass index, Chalson index, Glomerular filtration rate and osteoporosis grade.

Data analysis plan

OR for atypical femoral fracture risk associated to the use of bisphosphonates will be determined by logistic regression. Age, body mass index, smoking, alcoholism, malabsorption, rheumatoid arthritis, diabetes, thyroid disease and Charlson index and exposure to drugs will be covariates in a logistic regression model.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Data Warehouse (DWH) Southern Metropolitan Management Administration Area of the ICS is a database of medical records with administrative and healthcare proposes. The DWH integrates information from primary care contained in the E-CAP information system and from hospital care contained in the Argos information system.

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