

# 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:** 21/11/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS8463

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### Study ID

26997

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### DARWIN EU® study

No

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### Study countries

 Spain

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### Study description

Objectives: to evaluate the association between bisphosphonate use and the risk of atypical femoral fractures among women aged 50 or older. Design: 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.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

#### Bellvitge University Hospital

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

#### Bellvitge Biomedical Research Institute (IDIBELL)

 Spain

**First published:** 20/11/2025

**Last updated:** 20/11/2025

**Institution**

**Hospital/Clinic/Other health care facility**

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

Consuelo Pedrós

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 27/01/2015

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### Study start date

Planned: 02/03/2015

Actual: 02/03/2015

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### Data analysis start date

Planned: 01/01/2019

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## **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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**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

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**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)
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## **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, Chalon index, Glomerular filtration rate and osteoporosis grade.

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## **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

## 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)

[Other](#)

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#### 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

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### Check completeness

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No