Effectiveness of antiresorptives in preventing hip fractures in older women (≥ 75 years) with osteoporosis: nested case-control study cohort (BiHip)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/104775

EU PAS number

EUPAS104033

Study ID

104775

DARWIN EU® study

No

Study countries

☐ Spain

Study description

JUSTIFICATION: When antiresorptive came on the market, they had demonstrated efficacy in improving bone density. However, in most of the fundamental trials the results showed no clear potential benefit in reducing the risk of hip fracture. Several meta-analyses of antiresorptives have been carried out, reporting a statistically significant but clinically questionable benefit. HYPOTHESIS: The analysis of population cohort data has become a tool for assessing the real-life effectiveness of certain drugs. Antiresorptives may have a limited impact on preventing hip fractures in older osteoporotic women. GENERAL OBJECTIVE: To determine the real-life effectiveness of antiresorptive treatment in preventing hip fractures in older women (≥ 75 years) with osteoporosis. SPECIFIC OBJECTIVES: Analyze the risk of hip fracture in older women (≥ 75 years) with osteoporosis exposed to each group of collected antiresorptive versus those who do not have it. Analyze the risk of hip fracture in older women with osteoporosis exposed to antiresorptives versus those who do not have it, depending on when they receive treatment and its duration. The study will be nested case-control within a BIFAP cohort with the following inclusion criteria: Women aged ≥ 75 years. Diagnosis of osteoporosis Exclusion criteria History of cancer (excluding basal cell skin) Paget’s disease, rheumatoid arthritis, polymyalgia rheumatica or ankylosing spondylitis Patients taking oral corticosteroids for more than 3 months History of high impact trauma hip fracture Event: hip fracture Main exposure: antiresorptives Adjustment variables: confounding factors for osteoporosis

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Study status

Planned

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Cedeño Veloz Bernardo Abel

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/03/2023

Study start date

Planned: 10/05/2023

Date of final study report

Planned: 30/06/2023

Sources of funding

- EU institutional research programme
- Non-for-profit organisation (e.g. charity)
- Other

- Pharmaceutical company and other private sector

More details on funding

None, None, Osasunbidea, None, None

Study protocol

Protocolo del estudio V3 27-02-23.pdf(332.69 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Spanish Clinical Trials Registry ID: 0044-2023-OBS

https://reec.aemps.es/reec/observacional/0044-2023-OBS

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

GENERAL OBJECTIVE: To determine the real-life effectiveness of antiresorptive treatment in preventing hip fractures in older women (? 75 years) with osteoporosis.

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M05BA) Bisphosphonates

Bisphosphonates

(M05BA01) etidronic acid

etidronic acid

(M05BA02) clodronic acid

clodronic acid

(M05BA03) pamidronic acid

pamidronic acid

(M05BA04) alendronic acid

alendronic acid

(M05BA05) tiludronic acid

tiludronic acid

(M05BA06) ibandronic acid

ibandronic acid

(M05BA07) risedronic acid

risedronic acid

(M05BA08) zoledronic acid

zoledronic acid

Medical condition to be studied

Senile osteoporosis

Additional medical condition(s)

Substance abuse, Anxiety, Arrhythmia, Asthma, Ischemic heart disease, Depression, Type II diabetes mellitus, Celiac disease, Chronic obstructive pulmonary disease, Chronic kidney disease, Death, Hypertension, Hyperthyroidism, Hypothyroidism Stroke, Heart failure, Malignant neoplasm, Parkinsonism, Smoking Major, neurocognitive disorder

Population studied

Age groups

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

700000

Study design details

Outcomes

Hip fracture, Tibia and fibula fracture Nasal bone fracture Wrist fracture Vertebral fracture Humerus fracture

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Data analysis plan

We will use conditional logistic regression to estimate adjusted ORs and 95% CIs for the association between antiresorptive exposure and hip fractures. Antiresorptive use will be categorized as exposed vs non-exposed. In separate analyses, current use (current users) versus recent use (recent users) and past use (past users) will also be evaluated. Likewise, continuous and cumulative duration will be evaluated and results analyzed to identify a trend. The established significance level will be p=0.05. In the analysis by duration of exposure, the reference group will be never-users of antiresorptives. If a protective effect is found, an analysis of response duration (time-to-hip-fracture analysis) using log-rank test and Cox regression will be carried out.

Data management

Data sources

Data source(s)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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