Global burden of hip fractures – trends in incidence, post-fracture treatment, and mortality; a multicountry, observational study (20190532)

First published: 12/11/2020

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS37529

Study ID

50582

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Brazil
- ☐ Canada

- [ ] China
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hong Kong
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Netherlands
- [ ] New Zealand
- [ ] Singapore
- [ ] Spain
- [ ] Taiwan
- [ ] Thailand
- [ ] United Kingdom
- [ ] United States

Study description

This study aims to characterize hip fractures by year among men and women aged 50 years and above within multiple countries. Patient-level electronic health data will be derived from national or regional databases in 20 countries. Each database is estimated to provide at least several hundred hip fractures per year and up to tens of thousands of hip fractures per year. This study will use a retrospective cohort design, and will include patients who were hospitalized due to hip fracture during the study period. The study period was 14 years, from 1st January 2005 to 31st December 2018. Information will be collected to estimate the annual incidences of hip fractures. The proportion of patients having use of a pharmacological treatment for fracture prevention within 12 months following their initial hip fracture by year and the mortality

rate within 12 months following patients’ initial hip fracture by year, will also be estimated.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 14/08/2020

Actual: 14/08/2020

Study start date
Planned: 17/11/2020

Actual: 08/10/2020

Data analysis start date
Planned: 31/01/2022

Actual: 31/01/2022

Date of final study report
Planned: 31/07/2022

Actual: 21/10/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

EUPAS37529-38037.pdf(218.67 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

Protocol number 20190532

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To characterize hip fractures by year among men and women aged 50 years and above within multiple countries.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Medical condition to be studied

Hip fracture

Population studied

Short description of the study population

Patients hospitalized with hip fracture aged 50 years and older identified from 1st January 2005 to 31st December 2018.

Inclusion criteria:

o aged 50 years or above

o hospitalized due to hip fracture during the study period between 1st January 2005 and 31st December 2018

Exclusion criteria:

o diagnosis of hip fracture within 12 months before the initial fracture

o missing sex or age

o less than 12 months in the data source before the initial hip fracture

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Age groups

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

Patients with hip fracture

Estimated number of subjects

3000000

Study design details

Outcomes

To estimate the annual incidences of hip fracture. • To estimate the proportion of patient having use of a pharmacological treatment for fracture prevention within 12 months following their initial hip fracture by year. • To estimate the mortality rate within 12 months following patients' initially hip fracture by year.

Data analysis plan

The primary outcome will be calculated as the sum of hip fracture episodes in the year divided by the population at-risk in the year. A linear regression model will be used to test for time trends in the annual incidence proportion. Two-tailed $P<0.05$ will be considered statistically significant. For the 1st secondary outcome, the Kaplan-Meier method will be used to estimate the treatment proportion within 3, 6 & 12 months of fracture and 95% confidence intervals (CI), censoring patients on another hip fracture episode, 12 months, death, loss to follow-up, 31st December 2018 or the end of data available in a database, whichever earliest. For the 2nd secondary outcome, rate per calendar year of initial hip fracture will be calculated as the sum of patients who died of any cause during the 12-month follow-up period divided by the sum of patients with an initial hip fracture.

Documents

Study results

20190532 ORSR abstract_Redacted.pdf(491.16 KB)

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)

Disease registry

Electronic healthcare records (EHR)

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