Multinational Observational Database Study on Imminent Osteoporotic Fracture Risk: Stage 1 (IFRISK)

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Study Ongoing

Administrative details

EU PAS number

EUPAS23356

Study ID

24100

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Spain
- ☐ United Kingdom

Study description

Osteoporosis (OP) is a systemic skeletal disease characterized by low bone mass and bone structure deterioration leading to increased fracture risk. The main clinical complication of OP is increased susceptibility to fractures due to bone fragility. A number of guidelines propose oral bisphosphonates (BP) as first-line therapies to prevent fragility fractures in osteoporotic patients, and aim at reducing the risk of fractures by 50%. Some studies have been previously conducted and identified risk factors for imminent fracture in OP patients under BP therapy. However, some discrepancies were also found across studies.Another approach to early identify patients at higher risk of imminent fracture while under BP treatment is to use one of the predictive tools derived and validated in untreated populations, and to modify/calibrate them as needed. The QFracture risk score is a predictive tool derived in naïve patients for long-term risk fracture, that has been validated three times and updated in 2012. QFracture can also model 1-year imminent fracture risk, but its validity for such prediction has not been tested to date. The objectives of the study are:Primary: to undertake a comprehensive descriptive analysis of the six proposed high fracture risk subcohorts, in regards with clinical, social and socio-economic characteristics, and to estimate the 1-year and 2-year fracture incidence rates and cumulative incidence functions over time in the six defined subcohorts Secondary: to conduct an external validation of QFracture risk score in the six predefined high risk subcohorts (see below) for 1-year imminent fracture prediction, to estimate 1-year and 2-year incidence rates of fatal fracture, rates (in patients with linked hospital data available) of fracture-related hospitalizations, and mortality, and to study the anti-osteoporotic drug exposure during the follow-up period.

Study status

Ongoing

Research institutions and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Centre for Statistics in Medicine

University of Southern Denmark (SDU)

Denmark

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Institution | Educational Institution

University of Southern Denmark Odense, Denmark, Centre for Statistics in Medicine, NDORMS, University of Oxford Oxford, United

Kingdom, SIDIAP, Idiap Jordi Gol, Universitat Autonoma de Barcelona Barcelona, Spain

Contact details

Study institution contact

Daniel Prieto-Alhambra
daniel.prietoalhambra@ndorms.ox.ac.uk

Study contact

daniel.prietoalhambra@ndorms.ox.ac.uk

Primary lead investigator

Daniel Prieto-Alhambra

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/01/2017

Actual: 10/05/2017

Study start date

Planned: 01/10/2017

Actual: 01/10/2017

Data analysis start date

Planned: 01/02/2018

Actual: 01/02/2018

Date of final study report
Planned: 31/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Biopharma

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:

Disease epidemiology

Main study objective:

To undertake a comprehensive descriptive analysis of the six proposed subcohorts:• Describing the demographical, clinical characteristics of each subcohort.• Estimate 1-year and 2-year fracture incidence rates and cumulative incidence functions over time in the six defined subcohorts

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Osteoporosis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

750000

Study design details

Outcomes

Incident fracture during the 1 and 2 years follow-up period, per major osteoporotic sites, according to QFracture risk score definition (hip, spine, non-hip non-spine, hip/humerus/wrist). • Fatal fracture (during the 1- and 2-year follow-up period)• Fracture-related hospital admission (during the 1- and 2-year follow-up period)• All-cause mortality (during the 1- and 2-year follow-up period)• Drug exposure (during the 1- and 2-year follow-up period)

Data analysis plan

Each subcohort will be described according to a list of pre-specified variables, contingency tables will be drawn, 1-year fracture incidence rates and cumulative incidence function over time will be estimated for: osteoporotic fracture, fatal fracture, and hospitalization related to fracture. The analyses run in the six pre-defined cohort populations, separately in each datasets (CPRD, DHR, SIDIAP).Performance of the QFracture risk score for imminent fracture (1-year) will be examined in the six pre-defined cohort populations, by estimating the related indicators (see below). Of note, the analyses will be run separately in each dataset (CPRD, DHR, SIDIAP).

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

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