Hearing loss and risk of major osteoporotic fracture: a population-based cohort study in the United Kingdom (20200418)

First published: 07/01/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44961

Study ID

49608

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The overarching aim is to assess the association between hearing loss/impairment and fracture risk using the Clinical Practice Research Datalink (CPRD) and to generate a new short-term (1-year) as well as long-term (10-year) major osteoporotic fracture risk prediction tool for patients with hearing loss that will help clinicians to identify a population at high-risk of fracture.

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.
medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/04/2021

Study start date

Planned: 06/05/2022

Actual: 06/05/2022

Data analysis start date

Planned: 01/08/2022

Actual: 01/08/2022

Date of final study report

Planned: 31/03/2023

Actual: 17/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Our overarching aim is to assess the association between hearing loss/impairment and fracture risk, and to generate a new short-term (1-year) as well as long-term (10-year) major fracture risk prediction tool for patients with

hearing loss that will help clinicians to identify population at high-risk of fracture.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Osteoporotic fracture

Deafness

Population studied

Short description of the study population

The study population included patients aged 60 years or older diagnosed with hearing loss registered in the CPRD database from January 1, 2001 to December 31, 2020.

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

Frail population

Other

Special population of interest, other

Patients with hearing loss

Estimated number of subjects

200

Study design details

Outcomes

Major osteoporotic fracture: clinical spine, wrist/forearm, shoulder/proximal humerus, and hip fracture, Performance (calibration and discrimination) of major osteoporotic fracture (clinical spine, wrist/forearm, shoulder/proximal humerus or hip fracture) prediction tools for 1- and 10-years

Data analysis plan

Association analysis between hearing loss/impairment and fracture risk: absolute (incidence rate) and relative risk (proportional hazard Cox models) estimates of overall major fractures and of each major fracture subtype associated with hearing loss (hearing loss patients compared to matched unexposed subjects), stratified by age, sex, and high risk of fracture (prior history of fractures, OP diagnosis and/or anti-OP treatment). Risk factors with statistically significant interactions will be evaluated in sub-group analyses. Identification of the risk factors associated with 1- and 10-year major osteoporotic fracture risk amongst patients with hearing loss/impairment, and the consequent model development.

Documents

Study results

20200418 ORSR Abstract.pdf (179.42 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 source(s)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Linked Databases

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