

# 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

### PURI

<https://redirect.ema.europa.eu/resource/49608>

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### EU PAS number

EUPAS44961

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### Study ID

49608

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### DARWIN EU® study

No

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### Study countries

United Kingdom

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## 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.

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## 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.

Study contact

[medinfo@amgen.com](mailto: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

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### Study start date

Planned: 06/05/2022

Actual: 06/05/2022

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### Data analysis start date

Planned: 01/08/2022

Actual: 01/08/2022

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### 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

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

Not applicable

Methodological aspects

Study type

Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**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.

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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)

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## **Special population of interest**

Frail population

Other

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## **Special population of interest, other**

Patients with hearing loss

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## **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

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## **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\(179.42 KB\)](#)

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## Data management

### Data sources

#### Data source(s)

Clinical Practice Research Datalink

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#### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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#### Data sources (types), other

Linked Databases

### 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