DARWIN EU® - Chondrosarcoma: patient demographics, treatments, and survival in the period 2010-2023

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Finland



Administrative details

PURI https://redirect.ema.europa.eu/resource/1000000162
EU PAS number
EUPAS100000162
Study ID 1000000162
DARWIN EU® study Yes
Study countries

Study description

This study is aimed to describe demographics, treatments, and overall survival of patients with incident chondrosarcoma, stratified by age, sex, study period, country/database, and, if available, by the AJCC/UICC TNM (Tumour, Nodes, Metastases) classification system of malignant tumors (AJCC/UICC TNM) stage categories and histological grade in 2010-2023.

The specific objectives of this study are:

- 1. To describe demographic characteristics (age and sex) of patients with chondrosarcoma at the time of diagnosis.
- 2. To describe chondrosarcoma treatment options (drug therapy, surgery, and radiation, when available).
- 3. To estimate the overall survival of newly diagnosed chondrosarcoma patients during the study period (2010-2023).

Study status

Finalised

Research institutions and networks

Institutions

Networks

Data Analysis and Real World Interrogation Network
(DARWIN EU®)
Belgium
Croatia
☐ Denmark
Estonia
Finland
France
Germany
Hungary
☐ Netherlands
Norway
Portugal
Spain
United Kingdom

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Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/03/2024 Actual: 20/03/2024

Study start date

Planned: 24/05/2024 Actual: 03/06/2024

Date of final study report

Planned: 07/03/2025

Actual: 07/02/2025

Sources of funding

EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P2-C1-003_v3.1_Chondrosarcoma.pdf(840.73 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

A retrospective cohort study of all newly diagnosed chondrosarcoma cases will be conducted.

Main study objective:

To describe demographics, treatments, and overall survival of patients with incident chondrosarcoma, stratified by age, sex, study period, country/database, and, if available, by AJCC/UICC TNM stage categories and histological grade in 2010-2023.

The specific objectives of this study are:

- 1. To describe demographic characteristics (age and sex) of patients with chondrosarcoma at the time of diagnosis.
- 2. To describe chondrosarcoma treatment with medicines (chemotherapy and biologics) in patients that had undergone or not surgery, radiotherapy, both or neither.
- 3. To estimate the overall survival of newly diagnosed chondrosarcoma patients during the study period (2010-2023).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chondrosarcoma

Population studied

Short description of the study population

The study population will include all individuals with a first diagnosis of chondrosarcoma identified in each database between 01/01/2010 and 31/12/2023. Participants with a diagnosis of cancer (any, excluding non-melanoma skin cancer) or enchondroma before the diagnosis of chondrosarcoma will be excluded.

Age groups

ΑII

Paediatric Population (< 18 years)

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 - 27 days)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

This study will use routinely collected health data from 6 nationwide and regionwide databases in 5 European countries.

Documents

Study report

DARWIN EU_Report_P3-C1-003_Chondrosarcoma_V2.pdf(1.97 MB)

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)

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

Clinical Practice Research Datalink (CPRD) GOLD

Netherlands Cancer Registry

Clinical Data Warehouse of the Bordeaux University Hospital

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Use of a Common Data Model (CDM)

Yes
CDM Mappings
CDM name
OMOP
CDM website
https://www.ohdsi.org/Data-standardization/
Data quality specifications
Check conformance
Unknown
Check completeness
Unknown
Check stability
Unknown
Check logical consistency
Unknown
Data characterisation
Data Cilaracterisation
Data characterisation conducted
No

CDM mapping