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

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000162

EU PAS number

EUPAS1000000162

Study ID

1000000162

DARWIN EU® study

Yes

Study countries

Finland

France

Netherlands

Spain

United Kingdom

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:

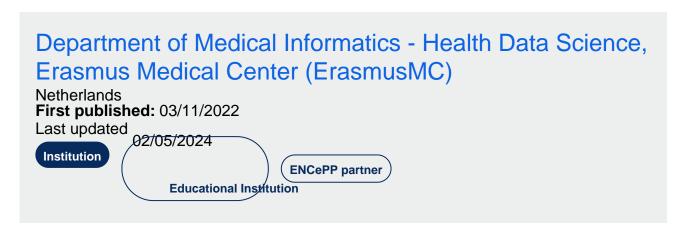
- 1. To describe demographic characteristics (age and sex) of patients with chondrosarcoma at the time of diagnosis.
- 2. To describe chondrosarcoma treatment options (drug therapy, surgery, and radiation, when available).
- 3. To estimate the overall survival of newly diagnosed chondrosarcoma patients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

Study status

Ongoing

Research institution 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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Network

Contact details

Study institution contact

Ilse Schuemie

Study contact

study@darwin-eu.org

Primary lead investigator

Talita Duarte-Salles

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:

30/08/2024

Sources of funding

EMA

Study protocol

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 list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary data collection

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 region-wide databases in 5 European countries.

Data management

Data sources

Data source(s)

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 (Care Register for Health Care)

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted No