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

First published: 16/05/2024
Last updated: 04/06/2024

Study | Ongoing

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

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands
First published: 03/11/2022
Last updated
02/05/2024

Institution
Educational Institution
ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

Belgium
Croatia
Denmark
Estonia
Finland
France
Germany
Hungary
Netherlands
Norway
Portugal

Spain
United Kingdom
First published: 01/02/2024
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Network

Contact details

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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:
30/08/2024

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 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
All
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