Osteonecrosis of the Jaw (ONJ) Case Registry

First published: 14/02/2014

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45163

EU PAS number

EUPAS5605

Study ID

45163

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Canada
- ☐ Denmark

- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

The purpose of the ONJ case registry is to describe the natural history of positively-adjudicated ONJ in subjects with cancer with an observation period of 5 years. Most of these subjects are expected to have received bone antiresorptive agents such as bisphosphonates or denosumab together with cancer-specific therapies (eg, chemotherapy, steroids, or anti-angiogenics). It is also possible that the registry will include subjects with cancer who developed ONJ without exposure to any antiresorptive therapy.

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

Primary lead investigator

Global Development Leader Amgen, Inc

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/07/2010

Study start date

Actual: 01/10/2012

Data analysis start date

Planned: 08/02/2021

Actual: 08/02/2021

Date of interim report, if expected

Planned: 01/09/2014

Actual: 06/11/2014

Date of final study report
Planned: 29/09/2021

Actual: 13/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20101102_Protocol_14Feb14.pdf(728.09 KB)

20101102_01.02.06 Public Redacted Protocol Ver 1.0 2018-07-19 English.pdf
(1.1 MB)

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To describe the natural history of positively-adjudicated ONJ in subjects with cancer with a 5-yr. observation period. Most of these subjects are expected to have received bone antiresorptive agents such as bisphosphonates or denosumab together with cancer-specific therapies. The registry may also include subjects with cancer who developed ONJ without exposure to any antiresorptive therapy.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series, Post-Marketing Safety Study

Study drug and medical condition

Medical condition to be studied

Osteonecrosis of jaw

Population studied

Short description of the study population

Investigators will be expected to maintain a screening log of all potential study candidates that includes limited information about the potential candidate such as sex, age, race, screening date, and outcome of the screening process (eg, enrolled into study, reason for ineligibility [eg, ONJ not positively adjudicated], or declined to participate). The rate of nonparticipation will be monitored during the trial. Before any study-specific procedure, the appropriate written informed consent will be obtained

Inclusion Criteria

1. Adult (≥ 18 years of age) with diagnosis of cancer
2. Newly diagnosed, positively-adjudicated ONJ
3. ECOG ≤ 2 and expected survival ≥ 3 months
4. Willing to provide access to previous and future medical and dental information
5. Subject or subject’s legally acceptable representative has provided written informed consent

Exclusion Criteria

1. History of radiation to the jaws administered for the treatment of cancer
2. Subject will not be available for protocol-required study visits, to the best of the subject and investigator’s knowledge
3. Subject has any kind of disorder that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent and/or to

comply with all required study procedures

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Cancer patients

Estimated number of subjects

327

Study design details

Outcomes

Resolution rate and time to ONJ resolution Time Frame: 5 years , Explore the relationship between rate and time to ONJ resolution with the following:ONJ severity and staging at Registry enrollment 5 yrs potential risk factors 5 yrs Explore the relationship between rate and time to ONJ resolution and the following:subsequent treatment patterns for ONJ 5 yrstreatment patterns of antiresorptive therapy 5 yrs

Data analysis plan

The objective of this study is to describe the natural history of positively-adjudicated ONJ in subjects with cancer. The primary endpoint is ONJ resolution and time course of resolution. Secondary endpoints include the clinical features of ONJ, including severity and staging at enrolment and the frequency of risk factors for incident ONJ. Continuous parameters will be summarized using descriptive statistics, which includes mean, standard deviation, median, and/or selected percentiles, and the number of non-missing observations. Categorical parameters will be summarized using frequencies and percentages. In general, analyses will be based on available data.

Documents

Study results

20101102_Observational_Research_Study_Report_Published_Report_Summary.pdf (288.89 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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