Estimation of Off-Label Use of XGEVA® (denosumab) Using Population-Based Databases in Denmark (20101335)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20211

EU PAS number

EUPAS5687

Study ID

20211

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

This study aims to evaluate off-label XGEVA use in Denmark using data linked from registries and other sources in Northern Jutland Region of Denmark. This will allow for accurate assessment of prescriptions and diagnoses, especially those related to cancer patients during the first year post the initial market availability of XGEVA.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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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: 15/11/2012

Study start date

Actual: 24/01/2013

Date of final study report

Actual: 03/11/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.20.01 Protocol Amend 2 2014-07-28 English.pdf(870.44 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Evaluation of XGEVA off-label use

Data collection methods:

Secondary use of data

Main study objective:

This study will evaluate off-label use of XGEVA® (denosumab) in Denmark during the first 1-year post XGEVA market availability, defined as 12 months after RADS opinion on 24th January 2013.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XGEVA

Medical condition to be studied

Off label use

Population studied

Short description of the study population

Patients with a treatment code for XGEVA in the Northern Jutland Region during the first 1-year period after the initial market availability of XGEVA.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Estimated number of subjects

108

Study design details

Outcomes

On or off label individual prescription type.On or off label patient treatment. Type of off-label use.Off-label use stratified by administering department

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Data analysis plan

Primary statistical analysis will be based on data of off-label use after the initial market availability of XGEVA in Denmark. Stratified analysis will be done for data accumulated during the first year of commercial availability. Additional analyses will stratify 12-month periods into 6-month intervals. Study population will be characterized with regard to demographic factors, diagnoses and treatments using descriptive statistics. Categorical variables will be summarized in frequency tables and numeric variables as the number of observations, mean, standard deviation, quartiles, and median.

Documents

Study results

20101335 ORSR Abstract_FINAL.pdf(27.41 KB)

Data management

Data sources

Data source(s)

Danish registries (access/analysis)

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown