EVENITY® Risk Minimisation Materials Effectiveness Measurement in Australia (20220120)

First published: 13/04/2023

Last updated: 13/05/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106263

EU PAS number

EUPAS104308

Study ID

106263

DARWIN EU® study

No

Study countries

☐ Australia

Study description

Study to measure the effectiveness of educational materials on awareness, utilization and adequacy targeted to medical professionals in addressing the cardiovascular risks associated with the use of EVENITY.

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
Planned: 01/12/2022

Actual: 01/12/2022

Study start date
Planned: 01/03/2023

Actual: 04/04/2023

Data analysis start date
Planned: 01/05/2023

Actual: 01/05/2023

Date of final study report
Planned: 15/04/2024

Actual: 03/04/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original romosozumab 20220120 (1).pdf(353.09 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The objective of this study is to measure the effectiveness of prescriber guide and patient alert card on awareness, utilization and adequacy targeted to HCPs in addressing the cardiovascular risks (myocardial infarction and stroke).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Study of responses to questionnaires on educational materials by medical professionals in Australia

Study drug and medical condition

Name of medicine

EVENITY

Study drug International non-proprietary name (INN) or common name

ROMOSOZUMAB

Anatomical Therapeutic Chemical (ATC) code

(M05BX06) romosozumab

romosozumab

Population studied

Age groups

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)

Estimated number of subjects

765

Study design details

Outcomes

Measure awareness of the educational materials, identify if specialists distribute the educational materials to their patients and/or caregivers when prescribing EVENITY, determine adequacy of the content of the education materials.

Data analysis plan

A market research vendor will conduct a survey to assess the effectiveness of the educational materials provided to Specialists. This survey will consist of a questionnaire targeted to Endocrinologists, Rheumatologists, Geriatricians and General Physicians in Australia who can prescribe EVENITY to patients. Study results will be in tabular form and aggregate analyses that omits subject identification.

Documents

Study report

20220120_ORSR_Abstract_Redacted.pdf(1.78 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Survey questionnaire targeted to Endocrinologists, Rheumatologists, Geriatricians and General Physicians in Australia who can prescribe EVENITY to patients.

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