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 institution 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
200000003495
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