An observational follow-up study for: a phase III randomized, placebo-controlled clinical trial to assess the safety and efficacy of odanacatib (MK-0822) to reduce the risk of fracture in osteoporotic postmenopausal women treated with vitamin D and calcium (Protocol 018) (MK-0822-083)

First published: 24/01/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5547

Study ID

47240

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Belgium
- [ ] Brazil
- [ ] Bulgaria
- [ ] Chile
- [ ] China
- [ ] Colombia
- [ ] Croatia
- [ ] Denmark
- [ ] Dominican Republic
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Guatemala
- [ ] Hong Kong
- [ ] India
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Latvia
- [ ] Lithuania
- [ ] Mexico
- [ ] New Zealand
- [ ] Norway
- [ ] Peru
- [ ] Philippines

- [ ] Poland
- [ ] Romania
- [ ] Russian Federation
- [ ] Serbia
- [ ] South Africa
- [ ] Spain
- [ ] Switzerland
- [ ] Taiwan
- [ ] Ukraine
- [ ] United States

Study description

This is a follow-up study to a placebo-controlled clinical trial (Protocol 018) designed to determine the safety and efficacy, especially fracture-risk reduction, of odanacatib in postmenopausal women with osteoporosis. The purpose of this follow-up study is to collect additional information on specific types of serious adverse events (SAEs) and AEs in those participants who discontinued from the Protocol 018 Base study, completed the Base study but did not enter the double-blind Extension, or discontinued from the double-blind Extension.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

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Institution

Biomelab Barranquilla, Colombia

Contact details

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/06/2013

Study start date
Actual: 03/10/2013

Data analysis start date
Planned: 08/07/2016

Actual: 23/07/2016

Date of final study report
Planned: 07/04/2017

Actual: 10/04/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme, LLC

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 type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

To collect and assess safety information for the double-blinded treatment period ending 5 years post-randomization regarding deaths, SAEs, AEs requiring adjudication, and skin events of clinical interest in participants who were randomized and took at least one dose of blinded study medication, then discontinued from study drug but have not completed follow-up

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional observational follow-up study of a randomized clinical trial

Study drug and medical condition

Medical condition to be studied

Osteoporosis

Population studied

Short description of the study population

Postmenopausal women with osteoporosis.

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

6000

Study design details

Outcomes

Number of participants with at least one Tier 1 adverse event

Data analysis plan

No analysis is planned for MK-0822-083 data alone. This study is purely observational. Summary statistics will be provided.

Documents

Study results

MK-0822-083_28-Apr-17_Synopsis_6.pdf(2.08 MB)

Data management

Data sources (types)

Other

Data sources (types), other

Targeted inquiry of an established cohort towards retrospective reporting

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