Effects of Lomitapide on Carotid and Aortic Atherosclerosis in Patients Treated with Lomitapide in Usual Care (CAPTURE)

First published: 21/04/2015

Last updated: 10/08/2017

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20500

EU PAS number

EUPAS7957

Study ID

20500

DARWIN EU® study

No

Study countries

☐ Canada

France

Italy

Netherlands

United States

Study description

The study is designed to evaluate the effects of lomitapide on carotid and aortic atherosclerosis in patients treated with lomitapide in usual clinical practice and who are enroled in the Lomitapide Observational Worldwide Evaluation Registry (LOWER).

Study status

Planned

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

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Contact details

Study institution contact

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Study contact

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Primary lead investigator

Janine Collins

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/01/2014

Actual: 16/09/2014

Study start date
Planned: 30/04/2015

Data analysis start date
Planned: 01/01/2016

Date of final study report
Planned: 26/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aegerion Pharmaceuticals

Study protocol

aegr-733-028-protocol 2 Apr 2014.pdf(658.42 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Methodological aspects

Study type

Study type list

Study type:

Clinical trial

Scope of the study:

Other

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

Evaluate the effects of lomitapide on carotid and aortic atherosclerosis in patients treated with lomitapide in usual clinical practice

Main study objective:

To assess the changes in atheroma burden as reflected by average carotid vessel wall area on MRI scanning following two years of treatment with lomitapide compared to baseline

Study drug and medical condition

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

LOMITAPIDE

Medical condition to be studied

Atherosclerosis prophylaxis

Population studied

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)

Estimated number of subjects

57

Study design details

Outcomes

The primary efficacy endpoint is the percent reduction from baseline in carotid vessel wall area at the two-year evaluation. Key secondary efficacy endpoints include the percent change from baseline to one and five years on therapy for carotid and aortic vessel wall area, and carotid and aortic vessel wall thickness.

Data analysis plan

The primary analysis will be a one-sample t-test on the within-subject percent reduction in average carotid vessel wall area using the modified intent-to-treat

(MITT) population. Descriptive statistics will also be presented, including the sample number, mean, median, standard deviation, minimum and maximum values, as well as a two-sided, 95% confidence interval. Absolute data values, including arithmetic change from baseline, will be presented descriptively, in addition to percent change from baseline. The same method of analysis as used for the primary efficacy endpoint will be used for secondary efficacy endpoints.

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