

# 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

### EU PAS number

EUPAS7957

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### Study ID

20500

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### DARWIN EU® study

No

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### Study countries

☐ Canada

☐ France

☐ Italy

☐ Netherlands

☐ United States

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### 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 enrolled in the Lomitapide Observational Worldwide Evaluation Registry (LOWER).

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### 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

[janine.collins@unitedbiosource.com](mailto:janine.collins@unitedbiosource.com)

### Primary lead investigator

Janine Collins

Primary lead investigator

# Study timelines

## **Date when funding contract was signed**

Planned: 17/01/2014

Actual: 16/09/2014

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## **Study start date**

Planned: 30/04/2015

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## **Data analysis start date**

Planned: 01/01/2016

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## **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

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**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

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**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

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**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)
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**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.

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**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

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Other](#)

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No