# An observational study to assess persistence on treatment, adherence, and patient-reported outcomes during the treatment of chronic hepatitis C genotype 1 infected patients with Boceprevir added to Peginterferon plus Ribavirin in Italy (MK-3034-137)

**First published:** 21/03/2014

**Last updated:** 02/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS6019

**Study ID**

47225

**DARWIN EU® study**

No

**Study countries**

Italy

**Study description**

This study is being done to evaluate persistence of triple-therapy treatment in Italian participants with genotype 1 (GT1) chronic hepatitis C (CHC) virus infections. Participants will be managed as per the clinical judgment of the treating physician with boceprevir (BOC) combined with pegylated interferon plus ribavirin (PR) in a real-life setting.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Merck Sharp & Dohme LLC

United States

**First published:** 01/02/2024

**Last updated:** 08/07/2025

Institution | Pharmaceutical company

### Univ Federico II Napoli

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Clinical Trial Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 16/09/2013

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**Study start date**

Planned: 07/04/2014

Actual: 16/04/2014

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**Data analysis start date**

Planned: 01/07/2016

Actual: 29/01/2016

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**Date of final study report**

Planned: 01/03/2017

Actual: 27/10/2016

## 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

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

Safety study (incl. comparative)

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

Persistence on treatment

**Data collection methods:**

Primary data collection

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**Main study objective:**

To estimate participant persistence on treatment in a real-life setting.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

BOCEPREVIR

PEGINTERFERON ALFA-2A

PEGINTERFERON ALFA-2B

RIBAVIRIN

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**Medical condition to be studied**

Chronic hepatitis C

## Population studied

**Short description of the study population**

Chronic hepatitis C genotype 1 infected patients with Boceprevir added to Peginterferon plus Ribavirin in Italy.

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**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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**Special population of interest**

Hepatic impaired

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**Estimated number of subjects**

210

# Study design details

**Outcomes**

Treatment persistence (Yes/No), duration of therapy to fallout (months), proportion of time participant was on treatment vs prescribed or expected treatment duration. Score on Medication Adherence Scale, boceprevir dose adherence, Health Related Quality of Life questionnaire score, work productivity and activity impairment, compliance with visit schedule.

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**Data analysis plan**

Statistical analysis will be descriptive using mean and standard deviation, median with maximum and minimum, or percentage as appropriate.

# Documents

**Study results**

Synopsis CSR Boceprevir final version.pdf(186.31 KB)

# 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

**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