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





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

Clinical Trial Disclosure Merck Sharp & Dohme LLC ClinicalTrialsDisclosure@Merck.com

Study contact

ClinicalTrialsDisclosure@Merck.com

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

Study start date

Planned: 07/04/2014

Actual: 16/04/2014

Data analysis start date

Planned: 01/07/2016

Actual: 29/01/2016

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

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

Study type:

Non-interventional study

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

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

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.

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)

Special population of interest

Hepatic impaired

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.

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 stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No