Practicalities of Using Boceprevir and Early Responses to Treatment: Experience of the First Eighteen Months In the UK. The Boceprevir Real LIfe Treatment (BRIT) study

First published: 01/10/2013

Last updated: 17/04/2014

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/6373

EU PAS number

EUPAS3669

Study ID

6373

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Evaluate the outcomes of the first two years' use of boceprevir in the UK and the early responses to treatment. This will be a retrospective study, based on data from the records of patients who received up to 12 weeks’ treatment for hepatitis C (genotype 1 infection) within a 2-year period.

Study status

Planned

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Chelsea and Westminster Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Royal Free Hospital

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Institution

Freeman Hospital Newcastle upon Tyne, Royal Bournemouth Hospital Bournemouth, Queen Elizabeth Hospital Birmingham, Derriford Hospital Plymouth, Glasgow Royal Infirmary Glasgow, Stirling Community Hospital Stirling, Chelsea & Westminster Hospital London, Royal Free Hospital London, Guy's & St Thomas' Hospital London

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Mayes Amazigom

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 05/11/2012

Study start date
Planned: 25/03/2013

Date of interim report, if expected
Planned: 17/04/2014

Actual: 04/09/2013

Date of final study report
Planned: 14/08/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD

Study protocol

10'4'13 BRIT Study_3rd amendment.pdf(465.78 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Explore how clinical management of HCV patients on triple therapy with boceprevir is being implemented in the UK, outside of the clinical trial setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Hepatitis C

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

100

Study design details

Outcomes

Assess PCR turnaround times, limits of detection (LOD) of PCR assays, and the length of the lead-in period, in clinical practice, estimate the proportion of subjects with early virologic responses at Weeks 4 (≥1 log10 drop), 8 and 12, determine the proportion of subjects adhering to futility rules (patients who discontinue all treatment at Week 12 due to insufficient viral response)

Data analysis plan

Descriptive analysis. Centre information and patient demographics summarised using tables and summary statistics.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective data from hospital records of eligible patients who have received treatment for hepatitis C. Data to be reviewed by treating clinicians.

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