A Post Approval Safety Study (PASS): Global Observational Cohort Study on the Prediction of Unwanted Adverse Effects in Individuals Infected with Chronic Hepatitis C Receiving a Long-Acting Interferon plus Ribavirin (GUARD-C)

First published: 20/06/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6725

Study ID

15700

DARWIN EU® study

No

Study countries

- Albania
- Algeria
- Bahrain
- Belgium
- Bosnia and Herzegovina
- Brazil
- Egypt
- Greece
- Hungary
- India
- Iran, Islamic Republic of
- Italy
- Korea, Republic of
- Kuwait
- Lebanon
- Morocco
- North Macedonia
- Pakistan
- Poland
- Portugal
- Qatar
- Romania
- Serbia
- Slovakia
- United Arab Emirates

Study description

This observational study will assess factors leading to dose reductions/treatment discontinuations and the effect on sustained virological response in patients with chronic hepatitis C receiving a long-acting interferon

(e.g. Pegasys/peginterferon alfa-2a) and ribavirin. Data will be collected from each patient for the duration of their treatment and for up to 6 months thereafter.

Study status

Finalised

Research institutions and networks

Institutions

IST GmbH

Multiple centres: 301 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

George Bakalos

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 09/08/2009

Study start date
Actual: 14/10/2009

Data analysis start date
Actual: 16/12/2013

Date of interim report, if expected
Actual: 28/10/2011

Date of final study report
Planned: 24/06/2014

Actual: 27/06/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

To assess in routine clinical practice (a) Baseline predictors for safety related dose reductions / treatment discontinuations and (b) The impact of safety-

related dose reductions / treatment discontinuations on SVR in subjects with CHC receiving combination therapy with a long-acting interferon plus ribavirin according to local label.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

PEGINTERFERON

RIBAVIRIN

PEGINTERFERON ALFA-2B

Medical condition to be studied

Chronic hepatitis C

Population studied

Short description of the study population

Adult subjects who were receiving treatment for Chronic Hepatitis C (CHC) with a long-acting interferon (alfa-2a or alfa-2b) plus ribavirin according to local standard-of-care and labeling with no contra-indication to long-acting interferon and ribavirin therapy, provided they had quantifiable serum HCV RNA by polymerase-chain reaction before initiation of treatment.

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

Other

Special population of interest, other

Chronic Hepatitis C patients

Estimated number of subjects

2500

Study design details

Outcomes

1.Correlation between baseline patient characteristics and safety related dose reductions/treatment discontinuations of the long-acting interferon or ribavirin Time frame: 4 years 2.Correlation between safety related dose reductions/treatment discontinuations and sustained virological response (SVR: defined as HCV RNA <50 IU/mL at 24 weeks after completion of treatment) Time frame: 4 years, 1.Correlation of on-treatment factors and dose reduction/treatment discontinuation Time frame: 4 years 2.Correlation between degree of dose reductions/treatment interruptions and SVR Time frame: 4 years 3.Comparison of on-treatment virological response in treatment-naïve and treatment experienced patients Time frame: 4 years 4.Safety: Incidence of

adverse events Time frame: 4 years

Data analysis plan

The principle analysis population will be the core population (treated patients excluding co-infection, no treatment, treatment-naïve but intended treatment duration of 72 wk). The analyses will be structured by pre-treatment status, treatment group, and intended treatment duration (24, 48 or 72 wk).The primary safety variable will be time to first safety related dose reduction (sr-DR). A Cox proportional hazard model will be used to examine the predictive value of various baseline factors on the primary and secondary safety variables of time to first sr-DR or treatment discontinuation. Kaplan-Meier estimation will be used to investigate the occurrence of sr-DRs or treatment discontinuations.Other safety variables (adverse events, laboratory values, etc) will be analyzed by descriptive statistics. Exploratory logistic regression analyses will be performed to investigate their impact on the dependent efficacy variable, sustained virological response.

Documents

Study results

Abstract from CSR MV22255 final report.pdf (83.51 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

Unknown