Utilization of Ribavirin in Pediatric Patients with Hepatitis C Virus - Aggregated Experience of European Specialists (MK-8908-060)

First published: 17/01/2014

Last updated: 27/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5533

Study ID

22864

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy

Spain

United Kingdom

Study description

This is a retrospective drug utilization survey, which collects data on the prescribing behavior of physicians treating pediatric patients for hepatitis C with ribavirin. Data collection will cover the time period from July 25, 2011 to July 24, 2014 in 5 European countries: Italy, France, Spain, Germany and the United Kingdom.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution | Pharmaceutical company

Multiple centres: 10 centres are involved in the study

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

ClinicalTrialsDisclosure@merck.com

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/07/2011

Study start date

Planned: 15/08/2014

Actual: 16/07/2014

Data analysis start date

Planned: 31/01/2015

Actual: 24/01/2015

Date of final study report

Planned: 10/03/2015

Actual: 19/03/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp and Dohme Corp

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The main objectives of the study are to estimate pediatric exposure to ribavirin solution and/or capsules among all children and adolescents with Hepatitis C (in proportions) and to describe demographic and disease characteristics of the pediatric population receiving ribavirin.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AB04) ribavirin

ribavirin

Medical condition to be studied

Hepatitis C

Population studied

Short description of the study population

Pediatric patients (age <18 years of age) with HCV infection who received at least one dose of ribavirin during routine clinical practice in the respective time period (between July 25th, 2011 and July 24th, 2014).

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Term newborn infants (0 – 27 days)

Special population of interest

Hepatic impaired

Estimated number of subjects

10

Study design details

Outcomes

The outcomes of interest in the pediatric population are the following: observation of prescribing behavior of ribavirin, utilization of ribavirin capsules and/or solution, demographic and disease characteristics of patients receiving ribavirin.

Data analysis plan

Study analyses will be limited to descriptive data on ribavirin prescriptions and treatment patterns as well as patient demographic and disease characteristics. Descriptive data analysis of the aggregated information will be performed and the results will be displayed in tabulated form (summarized and, whenever reasonable, on country-level). Analysis will be stratified by adolescents (12 to

<18 years) and non-adolescents (0 to <12 years).

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

This is a cross-sectional retrospective drug utilization study of a sample of at least 20 physicians (total of at least 10 study sites) throughout the specified countries.

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