A Long Term Follow-up Registry for Adolescent and Pediatric Subjects Who Received a Gilead Hepatitis C Virus Direct Acting Antiviral (DAA) in Gilead-Sponsored Chronic Hepatitis C Infection Trials

First published: 17/02/2017

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/25591

EU PAS number

EUPAS17875

Study ID

25591

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Belgium
- [ ] Germany
- [ ] Italy
- [ ] New Zealand
- [ ] Poland
- [ ] Russian Federation
- [ ] United Kingdom
- [ ] United States

Study description

GS-US-334-1113: Gilead Sciences is developing a number of novel antiviral agents targeting various components of the hepatitis C virus replication cycle and the Registry Study provided long-term assessment of safety and durability in pediatric subjects. Given the concern of the effect of current standard of care treatments (PEG and RBV) may have on growth and development in the pediatric population, the registry study specifically determined the effect of investigational anti-HCV regimens in the pediatric population as determined by assessments of growth and development. Lastly, the Registry was designed to provide long term clinical and virologic follow-up in subjects who have achieved SVR while participating in a previous Gilead-sponsored HCV study. This Registry also provided long-term follow-up to evaluate HCV viral sequences, and the persistence or evolution of viral mutations in subjects who did not achieve an SVR in a previous Gilead-sponsored chronic hepatitis C trial.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

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Institution | Pharmaceutical company

Multiple centres: 52 centres are involved in the study

Contact details

Study institution contact

Gilead Study Director

Study contact

GileadClinicalTrials@gilead.com

Primary lead investigator

Study Director Gilead

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/04/2015

Study start date
Actual: 21/10/2015

Date of final study report
Planned: 31/01/2025

Actual: 16/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences, Inc.

Study protocol

GS-US-334-1113-appendix-16.1.1-protocol_f-redact.pdf(876.81 KB)

GS-US-334-1113-appendix-16.1.1-protocol Amendment 3_f-redact.pdf(829.86 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

EudraCT Number: 2014-004674-42 (https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-004674-42)ClinicalTrials.gov identification number: NCT02510300 (https://clinicaltrials.gov/ct2/show/NCT02510300?term=NCT02510300&rank=1)

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Not applicable

Main study objective:

To determine the long-term safety of anti-HCV regimens in the pediatric population as determined by assessments of growth and development.

Population studied

Short description of the study population

The study focused on adolescent and pediatric subjects who received at least one Gilead hepatitis C virus direct acting antiviral (DAA) identified from the Gilead-sponsored chronic hepatitis C study.

Inclusion Criteria:

- Have previously participated in a Gilead-sponsored chronic hepatitis C study as an adolescent or pediatric subject and received at least one Gilead HCV direct acting antiviral (DAA);
- Parent or legal guardian able to provide written informed consent OR subject able to provide written informed consent and willing to comply with study requirements, as determined by IRB/IEC/local requirements and Investigator's discretion.
- Subject able to provide written assent, if they have the ability to read and write, as determined by IRB/IEC/local requirements and Investigator's discretion

Exclusion Criteria:

- Subject is currently receiving or plans to initiate a new course of hepatitis C therapy including any investigational drug or device during the course of the follow-up Registry.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

500

Study design details

Outcomes

Growth data by visit grouped by age and gender and development by Tanner Pubertal Stage Assessment. The proportion of subjects maintaining SVR.

Data analysis plan

Data from this Registry study was summarized descriptively. Statistical hypothesis testing was not conducted. All continuous variables were summarized using an 8-number descriptive summary (n, mean, standard deviation, and median, Q1, Q3, minimum, maximum) by visit. All categorical variables were summarized by number and percentage of subjects in each categorical definition.

Documents

Study results

GS-US-334-1113-CSR-synopsis_f-redact.pdf(724.29 KB)

Data management

Data sources

Data sources (types)

Disease registry

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