A Long Term Follow-up Registry for Subjects Who Achieve a Sustained Virologic Response to Treatment in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection

Published: 03-12-2012
Last updated: 26-04-2024

The primary objective of this Registry is:• To assess the durability of sustained virologic response (SVR) following treatment in a Gilead-sponsored hepatitis C study.The secondary objectives of this Registry are:• To determine whether subsequent...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON41568

Source
ToetsingOnline

Brief title
GS-US-248-0122: HCV SVR Registry

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym
Hepatitis C infection, liver disease

Research involving
Human

Sponsors and support

Primary sponsor: Gilead Sciences
Source(s) of monetary or material Support: Gilead Sciences Inc.

Intervention

Keyword: Follow-up Registry, Hepatitis C Infection, Sustained Virologic Response

Outcome measures

Primary outcome

The primary endpoints are:

• The proportion of subjects maintaining SVR at Week 144 per treatment regimen.

Secondary outcome

The secondary endpoints are:

• The proportion of subjects with detectable HCV RNA due to re-emergence of pre-existing virus through Week 144 per treatment regimen;

• The proportion of subjects with detectable HCV resistance mutations through Week 144 per treatment regimen;

• The proportion of subjects with detectable HCV RNA due to re-infection through Week 144 per treatment regimen;

• Liver Disease progression, as assessed by clinical and laboratory parameters;

• The proportion of subjects who develop HCC through Week 144 per treatment regimen.

Other endpoints of interest are:

• Route of re-infection, if known.

Study description

Background summary

See Protocol, page 9, section 1.1 Background

Study objective

The primary objective of this Registry is:
• To assess the durability of sustained virologic response (SVR) following treatment in a Gilead-sponsored hepatitis C study.

The secondary objectives of this Registry are:
• To determine whether subsequent detection of HCV RNA in subjects who relapse following SVR, represents the re-emergence of pre-existing virus, the development of resistance mutations, or whether it is due to re-infection;
• To assess clinical progression of liver disease;
• To screen for the development of hepatocellular carcinoma (HCC).

The exploratory objective of this Registry is:
• To assess quality of life following treatment in a Gilead-sponsored hepatitis C study.

Study design

This Registry will enroll subjects who have achieved an SVR after receiving at least one oral antiviral agent (OAV) while participating in a Gilead-sponsored hepatitis C clinical trial. The definition of an SVR is defined in the initial Gilead-sponsored treatment protocol. Once enrolled, subjects will be followed for up to 3 years. Visits will occur at Baseline and then at Weeks 24, 48, 72, 96, 120 and 144. At each visit, subjects will have blood drawn for plasma HCV RNA quantification, liver function tests, platelets, coagulation test, α-fetoprotein, and a quality of life survey will be completed. If HCV RNA is detected, the subject will have a repeat blood sample drawn for confirmation. If HCV RNA is confirmed the subject will be withdrawn from the Registry. If the confirmed HCV RNA is > 1000 IU/ml, viral sequence analysis will be performed.

Study burden and risks

Not applicable

Contacts

Public
Gilead Sciences

Lakeside Drive 333
Foster City CA 94404
US
Scientific
Gilead Sciences

Lakeside Drive 333
Foster City CA 94404
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Willing and able to provide written informed consent;
2. Have previously participated in a Gilead-sponsored hepatitis C study and received at least one Gilead oral antiviral agent (OAV);
3. Have achieved Sustained Virologic Response in a Gilead-sponsored study, as defined in the original treatment protocol;
4. Be willing and able to comply with the visit schedule and protocol-mandated procedures.

Exclusion criteria

Subjects who meet any of the following exclusion criteria are not to be enrolled in this Registry:

1. Subject plans to start a new course of hepatitis C therapy including any investigational drug or medical device during the course of the follow-up Registry.
2. History of clinically-significant illness or any other major medical disorder that may interfere with subject follow-up, assessments or compliance with the protocol.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2013
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	GS-7977 (not adminisered in this registry => observational study)
Generic name:	nvt

Ethics review

Approved WMO

Date:	03-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	26-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-000945-19-NL
CCMO	NL42225.018.12