A Long Term Follow-up Registry Study of Subjects Who Did Not Achieve Sustained Virologic Response in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection

Published: 19-12-2012
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The primary objective of this Registry is:• To evaluate HCV viral sequences and the persistence or evolution of treatment emergent viral mutations in subjects who fail to achieve an SVR after treatment with a Gilead oral antiviral containing regimen...

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

Summary

ID

NL-OMON41602

Source
ToetsingOnline

Brief title
GS-US-248-0123: HCV Sequence 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, No Sustained Virologic Response

Outcome measures

Primary outcome

The primary endpoints are:

• The proportion of subjects with at least one DRM loss from Enrollment to End

of Study by treatment regimen.

Secondary outcome

The secondary endpoints are:

• Proportion of subjects with DRM loss by unit category, 1, 2, 3,*n, by

treatment regimen;

• Average number of DRM loss by treatment regimen;

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

• The proportion of subjects who develop HCC through Week 144 by treatment

regimen.

Study description

Background summary

See Protocol, page 9, section 1.1 Background

Study objective

The primary objective of this Registry is:

• To evaluate HCV viral sequences and the persistence or evolution of treatment emergent viral mutations in subjects who fail to achieve an SVR after treatment with a Gilead oral antiviral containing regimen in a previous Gilead-sponsored hepatitis C study.

The secondary objectives of this Registry are:
• 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 failed to achieve an SVR after receiving at least one Gilead oral antiviral agent (OAV) while participating in a Gilead-sponsored hepatitis C clinical trial. The definition of failure to achieve an SVR is defined in the Gilead-sponsored treatment protocol, however, this Registry aims to include subjects whose HCV RNA:
• Failed to drop below the Lower Limit of Quantification (LLoQ) on treatment;
• Dropped below the LLoQ and then had a confirmed value above the LLoQ during treatment (breakthrough);
• Dropped below the LLoQ and then had a confirmed value above the LLoQ during the post-treatment follow-up period (relapse).

Once enrolled, subjects will be followed for up to 3 years. Clinic visits will occur at Baseline and at Weeks 12, 24, 36, 48, 96 and 144. At each visit, subjects will have blood drawn for plasma HCV RNA quantification, viral sequencing, liver function tests, platelets, coagulation test, α-fetoprotein, and a quality of life survey will be completed.

Viral sequences to be evaluated will be based on the specific antiviral agent(s) that the subject was treated with during the initial Gilead-sponsored treatment protocol.

Study burden and risks

Not applicable

Contacts

Public
Gilead Sciences

Lakeside Drive 333
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Scientific
Gilead Sciences

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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;
3 Have failed to achieve an SVR in a previous 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 is currently receiving or 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):	09-07-2014
Enrollment:	10
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	19-12-2012
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
Approved WMO Date:	22-04-2015
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	EUCTR2011-000946-39-NL
CCMO	NL42282.018.12