Long-Term Follow-Up of Subjects in a Phase 1, 2, or 3 Clinical Trial in Which Boceprevir or Narlaprevir was Administered for the Treatment of Chronic Hepatitis C.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON35269

Source
ToetsingOnline

Brief title
N.A.

Condition

- Viral infectious disorders

Synonym
Chronic Hepatitis C, Hepatitis C virus infection

Research involving
Human

Sponsors and support

Primary sponsor: Schering-Plough
Source(s) of monetary or material Support: Industrie: Schering-Plough Research Institute

Intervention

Keyword: boceprevir, CHC, genotype 1, narlaprevir

Outcome measures

Primary outcome

The primary endpoint in this study is the durability of virologic response in subjects with chronic hepatitis C who were sustained responders at 24 weeks posttreatment in the previous study. A subject is classified as a sustained responder at a given time point if HCV-RNA is below the lower limit of detection at that time point.

In addition, the study will also characterize the following:

* The long-term safety in subjects who received at least one dose of study medication in a previous Phase 1, 2 or 3 boceprevir of narlaprevir clinical study.

* The natural history of HCV sequence variants in subjects who received at least one dose of study medication in a previous Phase 1, 2 or 3 boceprevir of narlaprevir clinical study.

Secondary outcome

None

Study description

Background summary

New antiviral therapies that directly inhibit replication of the hepatitis C virus (HCV) are currently being developed. SCH 900518 and SCH 503034, hereafter known as narlaprevir and boceprevir, respectively, are novel members of the class of HCV non-structural protein 3 (NS3) protease inhibitors and are, therefore, members of a class of direct antivirals for the treatment of HCV. Treatment with either of these protease inhibitors in combination with peginterferon and ribavirin (RBV) may represent a new therapeutic option for patients with chronic hepatitis C
(CHC). The available information regarding the safety and efficacy of these regimens is derived primarily from ongoing studies. Therefore, little is known about the durability of the virologic response and long-term safety of this therapeutic regimen. In this protocol, subjects will be followed for 36 months after the end of their participation in a treatment protocol in order to evaluate the durability of the antiviral response (for sustained responders) and to characterize the long-term safety after use of one of these novel therapeutic regimens.
During the treatment protocols, subjects were evaluated for the development of HCV variants resistant to these novel agents. A number of resistant variants have been identified both in vitro and in vivo. However, the clinical significance of a greater proportion of such variants, and the effect of stopping therapy upon the specific pattern of HCV mutational variation, either known or suspected to confer resistance to narlaprevir or boceprevir, is not well established. In the present study, for subjects with detectable HCV RNA, sequence analyses will be performed at
regular intervals in order to characterize the natural history of these variants following treatment with these new antivirals. In general, these variants are usually less fit and, therefore, may be replaced by wild-type virus once the selection pressure of the direct inhibitor is removed.

Study objective

This study will be conducted in two parts as described below:
Part 1 will include subjects who participated in a Phase 1, 2, or 3 clinical study in which boceprevir was administered.
Part 2 will include subjects who participated in a Phase 1, 2, or 3 clinical study in which narlaprevir was administered.
Parts 1 and 2 have three primary objectives:
* Confirm the durability of the virologic response in subjects with chronic hepatitis C who were sustained responders 24 weeks post-treatment in the previous study.
* Characterize the long-term safety in subjects who received at least one dose of study medication in a previous Phase 1, 2, or 3 boceprevir or narlaprevir

clinical study.
* Characterize the natural history of HCV sequence variants in subjects who received at least one dose of study medication in a previous Phase 1, 2, or 3 boceprevir or narlaprevir clinical study

Study design

This is a long-term follow-up multicenter study in subjects in a Phase 1, 2, or 3 Clinical Trial in Which Boceprevir or Narlaprevir was Administered for the Treatment of Chronic Hepatitis C and have received at least one dose of any studymedication (peginterferon, ribavarin, boceprevir or narlaprevir). The study will be conducted in up to 215 sites worldwide. No drug therapy will be administered as part of this study.
There will be 8 scheduled study visits, the first 3 separated by 3-month intervals, and the last 5 separated by 6-month intervals.

Study burden and risks

No medication will be given under this protocol and the risks are minimal (only foreseeable risk is rare complication due to venous blood draw).

Burden patients: 8 vists 30-45 minutes per visit and 8 x blood draw

Since no treatment will be administered in this study, the benefits to the subject will be:
1. Long-term follow-up care to monitor if safety issues arise over the next 3 years,
2. Long-term follow-up care to monitor if any sustained responders from the previous study relapse over the next 3 years,
3. Long-term follow-up to characterize the natural history of HCV sequence variants in subjects who developed sequence variants while participating in a treatment protocol that included Boceprevir or Narlaprevir.

Indirectly, the subject's participation in this study may contribute to the further understanding of the treatment of chronic hepatitis C.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Subject must be willing to give written informed consent and be able to adhere to the visit schedule.
- Subject must have received at least one dose of any study medication (peginterferon, ribavarin, boceprevir or narlaprevir) in a previous SPRI Phase 1, 2 or 3 clinical study in which Boceprevir or Narlaprevir was administered.

Exclusion criteria

- Concurrent participation in any other clinical study for the treatment of chronic hepatitis C
- Retreatment with any antiviral or immunomodulatory drug for chronic hepatitis C after completion
of, or discontinuation from, the SPRI Phase 1, 2 or 3 clinical study in which the subject previously
participated.
- Any condition which in the opinion of the investigator would make the subject unsuitable for enrollment.

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2008
Enrollment:	9
Type:	Actual

Ethics review

Approved WMO Date:	24-06-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-08-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-11-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	16-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2014
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	EUCTR2006-006529-25-NL

Register	ID
CCMO	NL18104.018.08