A Long-Term Follow-Up Study of Subjects Who Participated in a Clinical Trial in which Peginterferon Lambda 1-a (BMS-914143) was Administered for the Treatment of Chronic Hepatitis C

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Recent studies demonstrate long-term durability of virologic response with pegylated alpha-interferon-based therapies. Comparable information is not yet available for Lambda or for regimens combining lambda interferons, RBV, and DAAs. In this...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40600

Source
ToetsingOnline

Brief title
AI452-016 Lambda Long Term Observational Follow Up Study

Condition

- Other condition
- Viral infectious disorders

Synonym
Chronic HCV, Chronic Hepatitis C Infection

Health condition

Hepatitis C

Research involving
Human

Sponsors and support

Primary sponsor: Bristol-Myers Squibb
Source(s) of monetary or material Support: Pharmaceutical industry

Intervention

Keyword: Chronic Hepatitis C, Liver Disease, Long Term, Virologic Response

Outcome measures

Primary outcome

Primary: To determine the durability of virologic response in subjects treated

in a previous study with Peginterferon lambda 1-a (BMS-914143; Lambda) with or

without ribavirin (RBV) and/or direct acting antiviral agents (DAAs), who have

HCV RNA less than the limit of quantitation of the assay (< LOQ) at the

completion of the required post-treatment follow-up in the previous (parent)

study.

Secondary outcome

Secondary:

To characterize the long-term progression of liver disease, as measured by

laboratory indicators of hepatic status and function, all-cause mortality, and

liver-related mortality, among subjects previously treated with Lambda

(BMS-914143) with or without RBV and/or DAAs, who have HCV RNA
completion of the required post-treatment follow-up in the parent study

To determine the duration of persistence of anti-Lambda antibodies in subjects

who are positive for anti-Lambda antibodies at end of treatment (EOT) in the

parent study

Study description

Background summary

Standard treatment options for patients with Hepatitis C virus (HCV) infection are limited. Current therapy involves 24-48 weeks of treatment with pegylated interferon alfa2a/alfa2b (Peg) and Ribavirin (RBV). This combination has limited effectiveness and is also poorly tolerated in some patients, highlighting the unmet medical need for new therapeutics. Treatment with BMS914143 is being studied with or without RBV and/or direct acting antiviral agents (DAA) for its role as a potential treatment option in combination therapy for patients with chronic hepatitis C (CHC). Little is known about the longterm safety and effectiveness of this combination in suppressing HCV, after study treatment has stopped. This study will follow patients previously treated in any BMS914143 study, for 3 years after their participation in the previous (*parent*) study has ended.

This study aims to assess whether the treatment received in the parent study will continue to be effective in suppressing HCV up to 3 years after study treatment has stopped. For patients where HCV is detected, this study will also determine if the virus that is present is less responsive to treatment. This study will also assess if patients liver disease worsens.

This study is designed to follow the timing of visits for patients that is consistent with standard of care for CHC. Participating patients will attend 7 clinic visits over 3 years (approximately every 6 months). During clinic visits patients will be asked about their lifestyle & medical history and will undergo a short physical examination and blood test. Phone contacts are also scheduled twice yearly. Globally, the study began in March 2012* and approximately 1000 patients will participate. In the Netherlands the study will begin in Jan2014* approximately 50 patients will participate. The total number of patients will increase with the addition of parent trials. The study is funded by Bristol-Myers Squibb.

Study objective

Recent studies demonstrate long-term durability of virologic response with pegylated alpha-interferon-based therapies. Comparable information is not yet available for Lambda or for regimens combining lambda interferons, RBV, and DAAs. In this protocol, subjects will be followed for up to approximately 3

years after the completion of their follow-up in a treatment protocol in order to evaluate the durability of the antiviral response and to characterize the long-term progression of liver disease after use of these novel therapeutic regimens.

Persistence of antibodies to biologic therapeutics based on endogenous proteins has potential impact on response to re-treatment with similar agents. In addition, there are theoretical concerns about potential impact on function of the endogenous protein. In the present study, the course of persistence or disappearance of anti-drug antibodies will be observed.

Study design

This study will follow subjects previously treated with Lambda in selected trials, including trials of Lambda used in combination with direct acting antiviral agents (DAAs).

Study burden and risks

Overall risk/benefit assessment

The burden, risks and potential benefits are summarised in Section E above.

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

Subjects must have received BMS-914143 in a previous trial and have HCV RNA < LOQ at the completion of the required post-treatment follow-up (must enter this study within 6 months of completion of the required post-treatment follow-up in the previous trial).

Exclusion criteria

Subjects must not have been treated with any antiviral or immunomodulatory drug for hepatitis C after completion of the previous study of BMS-914143.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2014
Enrollment:	26

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Peginterferon Lambda 1a
Generic name:	Peginterferon Lambda 1a

Ethics review

Approved WMO Date:	16-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2014
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	EUCTR2011-005293-31-NL
CCMO	NL46905.018.14