Ledipasvir and sofosbuvir for 8 weeks for the treatment of chronic hepatitis C genotype 4 in patients without cirrhosis. HepNed-001 study

Published: 03-02-2016
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To document that 8 weeks treatment with ledipasvir-sofosbuvir is effective in chronic HCV genotype 4 patients without cirrhosis.

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON43387

Source
ToetsingOnline

Brief title
HepNed-001

Condition

- Viral infectious disorders

Synonym
hepatitis C

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: genotype 4, hepatitis C, therapy

Outcome measures

Primary outcome

Sustained viral response 12 weeks after the end of therapy (SVR12) in

on-treatment study population with HCV RNA < 10.000.000 IU/ml at moment of

baseline visit (=start therapy).

Secondary outcome

SVR12 in ITT study population

SVR12 in the population with < 6 million IU/ml HCV RNA

SVR12 in the population with HCV RNA < limit of detection at week 4 of therapy

SVR12 in HIV positive population

Study description

Background summary

Recently, the phase III randomized clinical trial called ION-3, confirmed the data from the phase II LONESTAR trial and showed that for patients without cirrhosis and infected with HCV genotype 1, a treatment duration of 8 weeks with the direct acting antivirals (DAAs) ledipasvir and sofosbuvir is non-inferior to a 12-week regimen. The efficacy of a shortened treatment of 8 weeks for genotype 4 non-cirrhotic patients has never been studied. As the response rates in patients treated for 12 weeks for a HCV genotype 1 and 4 are very comparable, irrespective of the DAAs that were used (see table 1 in protocol), we postulate that the treatment duration in genotype 4 infected patients can be shortened to 8 weeks as well in non-cirrhotic patients.

Study objective

To document that 8 weeks treatment with ledipasvir-sofosbuvir is effective in chronic HCV genotype 4 patients without cirrhosis.

Study design

Prospective open label interventional clinical trial in which 50 chronic HCV genotype 4 patients co-infected with or without HIV will receive 8 weeks of Ledipasvir-Sofosbuvir in the Netherlands and Belgium (with at least 41 HIV-positive patients).

Intervention

Ledipasvir/sofosbuvir during 8 weeks

Study burden and risks

In general, therapy with these drugs was very well tolerated. In the ION-1,2,3 and 4 trials headache and fatique were most reported. In the ION-1, 2 and 4 trials, none of the patients treated with ledipasvir-sofosbuvir without ribavirine stopped due to AE*s[1-3]. The currently available treatment for hepatitis C genotype 4 consists of ledipasvir-sofosbuvir for 12 weeks, thus treatment for 8 weeks will be a lower burden for patients. There will be no additional visits of additional blood samples for patients compared to the current standard of care. The study will be beneficial for those patients that reach a SVR12 as they will be cured of HCV.

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

1. >=18 years
2. Chronic HCV genotype 4 infection
3. F0-3 with biopsy or fibroscan result (stiffness <12.5 kPa) <=24 months old for F0-2 and <=12 months old for F3*
4. HVC viral load < 10 million IU/ml, <=6 months old;**In case the HCV infection is <24 months old (=documented negative HCV IgG or negative HCV RNA < 24 months) and there is no HBV infection currently active or a history of alcohol abuse, then a fibroscan is not mandatory.

Exclusion criteria

1. HCV viral load > 10 million IU/ml
2. Fibroscan > 12.5 Kpa or F4 on liver biopsy or signs of portal hypertension or liver cirrhosis on imaging*
3. Disallowed co-medication that cannot be stopped or replaced
4. eGFR < 30 ml/min
5. Previous therapy with any DAA for current HCV genotype 4 infection;**In case the HCV infection is <24 months old (=documented negative HCV IgG or negative HCV RNA < 24 months) and there is no HBV infection currently active or a history of alcohol abuse, then a fibroscan is not mandatory.

Study design

Design

Study phase:	4
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2016
Enrollment:	35
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Harvoni
Generic name:	Ledipasvir/Sofosbuvir
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-02-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	09-03-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	25-04-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	20-05-2016

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-01-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-01-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21818
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-000318-31-NL
CCMO	NL56571.078.16
OMON	NL-OMON21818