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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21818

Source
NTR

Brief title
HepNed-001

Health condition

Chronic hepatitis C genotype 4.

Sponsors and support

Primary sponsor: dr. B. J. A. Rijnders, infectioloog, erasmus MC
Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

Sustained viral response 12 weeks after the end of therapy (SVR12) in on-treatment study population.

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

SVR12 in HIV negative population compared to SVR12 in HIV positive population

Study description

Study objective

OBJECTIVE: To document that a 8 week treatment with Ledipasvir-Sofosbuvir in patients chronically infected with HCV genotype 4 but without liver cirrhosis is effective.

Study design

Screening, Baseline, Week 4, Week 8 (end of therapy), Week 20 (SVR12).

Intervention

Ledipasvir and Sofosbuvir, 8 weeks

Contacts

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Eligibility criteria

Inclusion criteria

1. ¡Ý18 years

2. Chronic HCV genotype 4 infection according to definition mentioned below

3. F0-3 with biopsy or fibroscan result (stiffness <12.5 kPa) ¡Ü24 months old for F0-2 and <12 months old for F3

4. HVC viral load < 10 million IU/ml, ¡Ü6 months old.

Definition of chronic hepatitis C infection: The diagnosis of chronic hepatitis C is based on the detection of both anti-HCV antibodies or HCV RNA present for more than 6 months. Since, in the case of a newly acquired HCV infection, spontaneous viral clearance is rare after the first 6months of infection, the diagnosis of chronic hepatitis C can be made at that time (as stated in the EASL clinical practice guideline ¡°Recommendations on treatment of hepatitis C 2015¡±).

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: Therefore ALL co-medication, including over-the-counter drugs should be checked for potential drug-drug interactions using the summary of product characteristics (appendix A). When in doubt about drug-drug interactions, contact the coordinating investigator.

4. eGFR < 30 ml/min

5. Previous therapy with any DAA for current HCV genotype 4 infection

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-03-2016
Enrollment:	41
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-03-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43387
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5622
NTR-old	NTR5729
CCMO	NL56571.078.16
OMON	NL-OMON43387

Study results