Effect of ASV and DCV therapy on the quality of immune status in chronic HCV patients;Investigator initiated research proposal nr. AI447-108

Published: 04-09-2013
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To evaluate in detail the functionality of immune cells in blood in chronic HCV patients before, during and after treatment with ASV and DCV, in an IFN-free regimen.

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

Summary

ID

NL-OMON40207

Source
ToetsingOnline

Brief title
Immuno Dual

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym
hepatitis C

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Maag-, Darm en Leveronderzoek (SLO)

Source(s) of monetary or material Support: BMS,Stichting Leveronderzoek;Rotterdam (SLO) en BMS

Intervention

Keyword: antiviral therapy, HCV, immune response, viral hepatitis

Outcome measures

Primary outcome

To evaluate in detail the functionality of immune cells in blood in chronic HCV patients before, during and after treatment with ASV and DCV, in an IFN-free regimen.

The following questions will be addressed in this study:

1. Does the reduction in viral load due to dual therapy with ASV and DCV affect the immune status of patients chronically infected with HCV?

2. Does the reduction in viral load due to dual therapy with ASV and DCV restore impaired immune responses to HCV?

Secondary outcome

not applicable.

Study description

Background summary

Worldwide approximately 170 million people are infected with the hepatitis C virus (HCV). Current treatment consists of peginterferon and ribavirin which ensures a sustained viral response (SVR) in approximately 50% of patients with genotype 1. Recently, telaprevir or boceprevir was added to this treatment, but there are many side effects as a result of the activity of of interferon in the therapy. With this research we want to study two novel antiviral compounds, ASV

and DCV, that act directly on inhibiting the replication of the virus.

Study objective

To evaluate in detail the functionality of immune cells in blood in chronic HCV patients before, during and after treatment with ASV and DCV, in an IFN-free regimen.

Study design

Single center, open label study with one arm of 12 patients.
Patients are between 18 and 70 years of age, with a chronic hepatitis C - genotype 1b infection.

Study burden and risks

The risk and discomforts experienced during participation to the study (treatment and extra blood collection) are minimal.

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

• Patients between 18 and 70 years of age, with a chronic hepatitis C - genotype 1b infection;• Patients are non-responders to previous treatment with peginterferon or conventional interferon plus ribavirin combination therapy;• High viral load (>400,000 IU/ml);• Indication for antiviral therapy of hepatitis C according to current clinical guidelines;• Written informed consent

Exclusion criteria

• Decompensated cirrhosis (Child-Pugh Grade B or C);• Hepatic imaging (ultrasound, CT or MRI) with the evidence of hepatocellular carcinoma within the last 3 months.;• Females who are pregnant or breast-feeding;• History or other evidence of severe illness, malignancy or any other condition which would make the patient, in the opinion of the investigators, unsuitable for the study;• Co-infections with human immunodeficiency virus (HIV) or Hepatitis B virus (HBV);• Presence of contra-indications for antiviral therapy with ASV and DCV: ;• Interfering substance abuse, such as high alcohol intake (indicator: 28 drinks/ week);• Any exposure to NS3 protease inhibitors or NS5A polymerase inhibitors;• Treatment with peginterferon/ ribavirin within 6 months before start of therapy;• Any other condition which in the opinion of the investigator would make the patient unsuitable for enrollment, or could interfere with the patient participating and completing in the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2014
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	HCV NS3 Protease Inhibitor
Generic name:	Asunaprevir
Product type:	Medicine
Brand name:	HCV NS5A Replication Co-Factor Inhibitor
Generic name:	Daclatavir

Ethics review

Approved WMO Date:	04-09-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-12-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-02-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-02-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	18-12-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-02-2015
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-002991-42-NL
CCMO	NL45667.078.13