Association between IL28B polymorphisms and outcome of treatment for acute hepatitis C in HIV-patients

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The objective of the study is to investigate the association between IL28 SNPs and the outcome of acute HCV treatment (response or non-response) in HIV-infected patients.

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

Summary

ID

NL-OMON34931

Source
ToetsingOnline

Brief title
IL28B NSP in acute HCV

Condition

- Viral infectious disorders

Synonym
IL28B single nucleotide polymorfism (SNP), IL28B substitution

Research involving
Human

Sponsors and support

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

Intervention

Keyword: acute HCV, IL28B, SNP

Outcome measures

Primary outcome

Association between IL28B SNPs and outcome of acute HCV treatment.

Secondary outcome

not applicable

Study description

Background summary

Recently, several studies have identified a few polymorphisms (SNPs) upstream of the IL28B gene to be associated with the outcome of chronic hepatitis C virus (HCV) treatment. However, to date no data exist about any possible association between these polymorphisms and the outcome of acute HCV therapy. In contrast to combination therapy with peginterferon-alfa/ ribavirin (pegIFN/RBV) for chronic HCV infection, the optimal treatment for acute HCV is being debated (combination therapy or mono-therapy pegIFN). In our unique cohort treated with pegIFN mono-therapy we have a very high rate of non-response. Therefore, we hypothesize that polymorphisms in the IL28B region previously associated with clearance and non-response in chronic HCV treatment are associated with non-response with pegIFN mono-therapy for acute HCV.

Study objective

The objective of the study is to investigate the association between IL28 SNPs and the outcome of acute HCV treatment (response or non-response) in HIV-infected patients.

Study design

Cohort study of HIV-infected patients treated for acute HCV in which single measurement of IL28B SNPs will be performed.

Study burden and risks

10mL of blood will be obtained all 19 patients in this cohort. Those patients with a non-response to therapy will benefit from participation because information regarding their IL28B polymorphisms will possibly influence the decisions regarding their future therapy for chronic HCV.
For the few patients successfully treated for acute HCV there is no direct benefit in participation.
However, for all patients counts that the burden and risk of taking 1 blood sample during regular blood measurements is 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

all HIV-infected patients seen at the two outpatient clinics (UMCU and UMCG) (having been) treated with peginterferon-alfa mono-therapy for acute HCV.

Exclusion criteria

none, it's a excisting cohort of 19 treated patients with acute HCV and HIV

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):	16-06-2010
Enrollment:	19
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL31868.041.10