Time to diagnosis of HCV re-infection with the use of a self-test. A feasibility study.

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To assess the effectivity and feasibility of HCV RNA self-testing in reducing the time to diagnosis of HCV re-infection in MSM previously cured of an HCV infection, compared to the current diagnostic standard of care. To evaluate whether the uptake...

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

Summary

ID

NL-OMON48141

Source
ToetsingOnline

Brief title
SELFIE

Condition

- Viral infectious disorders

Synonym
HCV infection, Infection with the hepatitis C virus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Gilead Sciences

Intervention

Keyword: acute hepatitis C, Hepatitis C, men having sex with men, reinfection

Outcome measures

Primary outcome

Comparison of the time to HCV re-infection diagnosis in patients using the HCV RNA self-test (intervention) with the time to HCV re-infection diagnosis with the standard diagnostic approach (virtual control) in the modified intention to treat population.

Secondary outcome

1. Comparison of the time to HCV re-infection diagnosis in patients using the HCV RNA self-test (intervention) with the time to HCV re-infection diagnosis with the standard diagnostic approach (control) in the subpopulation that sent in all planned self-tests during their entire follow-up (Per protocol analysis).

2. Of the HIV+MSM that were offered to participate in the study, the percentage that accepted to participate and eventually self-collected and sent in at least one plasma sample in each 12-month period of study participation.

3. Overall incidence of HCV re-infection in the entire study population regardless of the type of HCV diagnostic test that was used.

4. Number of newly diagnosed HCV infections at the time of the screening visit as a result of a positive HCV RNA test at the screening visit.

Study description

Background summary

Elimination of HCV was recently formulated as a WHO target and was set for the year 2030. Globally, approximately 6.2% of HIV-infected patients are co-infected with HCV. Of the patients living with HIV, people who inject drugs (PWID) and men who have sex with men (MSM) are at particularly high risk of HCV co-infection. However, as a result of the early adaptation of opioid substitution and needle exchange programs in the Netherlands, the number of PWID co-infected with HIV and HCV is limited. This is unfortunately not the case for HIV-infected MSM. Until recently, the prevalence of chronic HCV in Dutch HIV+MSM was very high at 4,8% (compared with 0.2% in the Dutch population in general). However, after the restrictions on the use of direct-acting antivirals against HCV (DAA) were lifted in 2015, the prevalence of chronic HCV in HIV+MSM decreased rapidly. With this decreasing prevalence of chronic HCV a decrease in the incidence of acute HCV infections in Dutch HIV+MSM was observed as well. Indeed, while the incidence of acute HCV in HIV+MSM in care in the Netherlands was 1.1% in 2014, this decreased by 51% in 2016. However, no further decline in the number of acute HCV infections was observed in 2017. Also, the incidence of HCV re-infections in HIV+MSM that were cured of a previous HCV infection continues to be very high in the DAA era with reported rates varying between 5-10% per year.

The continuously high re-infection risk and the lack of a further decline in the HCV incidence after 2016 illustrates that universal DAA therapy for all patients diagnosed with a chronic HCV infection on its own will not result in HCV elimination. Other interventions are needed to reach the WHO goal of HCV elimination by 2030. One of these additional interventions may be decreasing the time to diagnosis of HCV re-infections in order to decrease the duration that these re-infected patients may transmit their HCV to sex partners. Indeed, if the diagnosis of HCV re-infection is made earlier, counseling on transmission risk in combination with the prompt initiation of HCV therapy will prevent transmission to sex partners and prevent new HCV infections on the population level.

The study we describe here was designed to evaluate the effect and feasibility of more frequent and home-based testing for HCV on the time to diagnosis and treatment of HCV re-infections.

Study objective

To assess the effectivity and feasibility of HCV RNA self-testing in reducing the time to diagnosis of HCV re-infection in MSM previously cured of an HCV infection, compared to the current diagnostic standard of care.

To evaluate whether the uptake of self-testing is sufficient and warrants the use of HCV RNA self-testing in clinical practice.

Study design

Prospective controlled intervention trial. MSM cured of an HCV infection who are at continued risk for an HCV re-infection (based on the results of a short questionnaire) are offered HCV RNA self-testing and asked to use the test every 6 months for 2 consecutive years.

Intervention

Eligible patients are instructed on the use of a capillary blood self-collection kit. They receive 2 kits per year for 2 consecutive years to allow them to send plasma to the virology lab of the Erasmus MC every 6 months by regular post mail.

Study burden and risks

The burden associated with participation in the study consists of taking a finger prick blood sample for the home-based test 4 times in 2years and sending the sample to the laboratory by regular post mail. No costs will have to be made for mailing the sample. Capillary finger-prick blood sampling is used as a standard diagnostic test for many diseases (e.g. glucose monitoring in diabetes) and is associated with a negligible risk. The study may potentially be beneficial for those participants in which a HCV reinfection is diagnosed as they will be referred for counseling and HCV therapy, so that transmission to sex partners could be avoided.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Cured of HCV defined as an SVR (=documented negative HCV RNA test) at least 12 weeks after the end of DAA therapy and no new documented positive HCV RNA test after the date of the SVR, OR, Spontaneous clearance of HCV infection defined as two consecutive negative HCV RNA tests at least 3 months apart after a positive HCV RNA test. , - In care for an HIV infection in an HIV clinic in the Netherlands or Belgium or HIV negative and receiving PrEP at a PrEP clinic, - Able and willing to perform the self-test at home after viewing the instruction video, - Willing to fill out a questionnaire on risk behavior at the time of home-based HCV testing , - At risk of HCV reinfection according to a short questionnaire, in other words, patients should have one of the following risk factors (19):
o Receptive unprotected (condomless) anal intercourse in the last 6 months
o Fisting or being fisted without gloves in the last 6 months
o Sharing toys in the last 6 months
o Syfilis or LGV in the last 12 months,
o Slamming (injecting drug use) in the last 12 months
o Sharing sniffing straws or other objects to sniff drugs in the last 12 months

Exclusion criteria

- Age <18 years old, - Patients that are tested by HCV RNA as a standard of care test (e.g. in the context of PREP use) > 1x/year, - Patients that are expected to be tested by ALT at their HIV or PREP clinic <1x/year

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-07-2019
Enrollment:	145
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	30-12-2019
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
CCMO	NL67745.078.18

Study results

Date completed: 16-12-2021

Summary results
Trial ended prematurely