Interventions to curb hepatitis C reinfections among men who have sex with men.

Published: 31-07-2019
Last updated: 09-04-2024

To evaluate interventions aimed at reducing risk behaviour, and ultimately preventing HCV reinfections and onward spread of HCV.

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

Summary

ID

NL-OMON54537

Source
ToetsingOnline

Brief title
ICECREAM study

Condition

- Viral infectious disorders

Synonym
HCV infection, Hepatitis C virus infection

Research involving
Human

Sponsors and support

Primary sponsor: GGD Amsterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Hepatitis C virus infection, Intervention, Prevention, Reinfection

Outcome measures

Primary outcome

The primary outcome is the proportion at risk of HCV reinfection (as determined by a HCV-MOSAIC risk score >= 2) during the run-in versus intervention periods. This risk score consists of 6 items related to the risk of HCV and is calculated by summing up the bèta's of the items when present in the past 6 months:

1. Receptive condomless anal sex (beta 1.1)

2. Sharing of sex toys (beta 1.2)

3. Unprotected fisting (beta 0.9)

4. Injecting drug use (beta 1.4)

5. Sharing of straws during nasally-administered drug use (beta 1.0)

6. Ulcerative sexually transmitted infection (beta 1.4)

Secondary outcome

Secondary outcomes include HCV reinfection incidence, changes in individual risk behaviour items of the HCV-MOSAIC risk score and changes in sexual wellbeing.

Study description

Background summary

As highly effective therapy against hepatitis C virus (HCV) infection is available with rapid uptake, there is newfound optimism for HCV elimination.

Nevertheless, HCV reinfections cause great concern in at risk populations, including men who have sex with men (MSM). In the Netherlands, MSM account for the majority of new HCV (re-)infections. Although HCV treatment uptake is high in this group, modelling data indicate HCV elimination would not be feasible without a reduction in risk behaviour. This finding highlights the urgent need for effective interventions aimed at reducing risk behaviour and preventing reinfections in MSM.

Study objective

To evaluate interventions aimed at reducing risk behaviour, and ultimately preventing HCV reinfections and onward spread of HCV.

Study design

Using a 3-arm randomised trial comparing run-in and intervention periods, we will evaluate the effect of two interventions, alone and its combination, on risk behaviour in MSM previously infected with HCV.

Intervention

Intervention I is a targeted, online behavioural intervention developed as part of the project. Intervention II consists of an additional patient-initiated, home-based HCV RNA testing service with the use of self-sampled dried blot spots. Intervention III is a combination of intervention I and II.

Study burden and risks

One site visit will be required for all participants to sign the informed consent form, which will be a routine visit at the HIV treatement center or STI/PrEP/sexual health center. All further study procedures will be web-based or will take place at home. Participants will be exposed to five online questionnaires, with an interval of 6 months. The interventions might make participants more aware of their HCV risk. However, we think this study poses negligible risk to the participants.

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

- Men who have sex with men >= 18 years
- History of a prior HCV infection (succesfully treated or spontaneously cleared)

Exclusion criteria

- Acute or chronic HCV infection at time of enrolment (positive HCV RNA).
- Under HCV treatment at time of enrolment.
- Unlikely, in the opinion of the clinician, to comply with the study procedures.
- Currently participating in an intervention study that offers extra HCV testing and/or a behavioural intervention.
- Investigators and other dependent persons.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-11-2019
Enrollment:	246
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-08-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL68718.018.19