

# Hepatitis C virus transmission dynamics among MSM in Amsterdam: the MSM Observational Study of Acute Infection with hepatitis C.

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Objective: - describe and monitor the molecular epidemiology of HCV in MSM in Amsterdam- determine HCV transmission networks in MSM- determine the factors associated with HCV transmission networks- determine role of HIV positive MSM who acquire...

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

## Summary

### ID

NL-OMON48160

### Source

ToetsingOnline

### Brief title

The MOSAIC cohort

### Condition

- Viral infectious disorders

### Synonym

Hepatitis C, inflammation of the liver

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Hepatitis C Virus, MSM, Transmission

## Outcome measures

### Primary outcome

- Dynamics of the phylogenetic transmission clusters
- Sexual network related parameters including timing, location, and method of meeting sexual partners

### Secondary outcome

not applicable

## Study description

### Background summary

Despite impressive uptake of direct-acting antivirals for Hepatitis C virus (HCV) in the Netherlands among HIV/HCV co-infected men who have sex with men (MSM), HCV transmission continues, especially among patients previously successfully treated for HCV. The incidence of reinfection occurs at the extremely high rate of 15 per 100 person-years. Moreover, HCV transmission also occurs in high risk HIV negative MSM, particularly in PrEP users. Clearly, to eliminate HCV from the MSM population, more information is needed on transmission dynamics to identify the sources and timing of new HCV infections. Real-time information on transmission dynamics could guide public health services in their preventive efforts.

### Study objective

Objective:

- describe and monitor the molecular epidemiology of HCV in MSM in Amsterdam
- determine HCV transmission networks in MSM
- determine the factors associated with HCV transmission networks
- determine role of HIV positive MSM who acquire acute HCV in HCV transmission to HIV negative MSM (including MSM taking PrEP)

- monitor changes in sexual network characteristics over time

## Study design

Open prospective observational cohort. The study is the reduced and revised version of the MOSAIC-2 cohort study that started in 2009 (NL26485.018.09, AMC MEC 09/023).

## Study burden and risks

Data collection for this study will be performed as much as possible in accordance with the diagnostic interventions in the regular care of these patients. For individuals with an acute HCV infection, extra interventions for data collection will consist of:

- Extra serum collection during regular venapunctions after acute infection
- Filling in a questionnaire on timing, location, and method of meeting sexual partners in the past 6 months at inclusion and during 2-year follow-up

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- o Male
- o Having sex with men
- o 16 years or older
- o With or without HIV infection
- o Acute HCV infection according to our definition
- o Presumed acquisition of acute HCV infection via sexual transmission

### Exclusion criteria

Inability or unwillingness to provide informed consent or follow the requirements of the study

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 25-11-2019

Enrollment: 250

Type: Actual

## Ethics review

Approved WMO	
Date:	10-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	03-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-10-2019
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	NL70267.018.19