# Sequelae of acute hepatitis C virus infection among HIV positive MSM, HIV negative MSM and HIV positive heterosexuals: the MOSAIC cohort.

Published: 19-01-2015
Last updated: 20-04-2024

To study a cohort of HIV infected and HIV uninfected MSM and HIV infected heterosexuals who (subsequently) acquired HCV infection with a known date of HCV seroconversion:1. To identify the frequency, clinical consequences and determinants (viral and...

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

## Summary

### ID

NL-OMON45164

**Source**
ToetsingOnline

**Brief title**
the MOSAIC cohort

### Condition

- Hepatic and hepatobiliary disorders
- Immunodeficiency syndromes
- Viral infectious disorders

**Synonym**
inflammation of the liver, viral hepatitis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** AbbVie,AIDS fonds en Research & Development GGD Amsterdam,Gilead Sciences

## Intervention

**Keyword:** hepatitis C virus, HIV, men who have sex with men (MSM)

## Outcome measures

**Primary outcome**

1 Frequency and determinants of acquiring primary , re- and superinfection with HCV (sociodemographic, clinical, behavioural, virological, immunological and genetic variables)

2 A: HCV viral load dynamics according to treatment status and other determinants

B: Proportion of patients with Rapid Virological Response (RVR), Early Virological Response (EVR) and Sustained Virological Response (SVR), defined by current and future (inter)national guidelines, according to weeks of treatment or weeks post therapy

C: Predictors for Virological Response

3 A: Morbidity following acute HCV and its determinants in HIV infected and HIV-uninfected individuals

B: Mortality following acute HCV and its determinants in HIV infected and HIV-uninfected individuals

4 Overlap between HIV and HCV epidemics

5 Driving factors for the HCV outbreak including sociodemographic, behavioural

and biological variables

**Secondary outcome**

1. A: Probability of achieving HCV clearance in the absence of therapy

B: Predictors of HCV clearance based on sociodemographic, clinical,

virological, immunological and genetic variables

2. HCV-specific immunology: T-cells, B-cells and the innate responses

3. Time to HCV antibody seroconversion and its determinants

4. Response to cART in HIV/acute HCV coinfection, defined as short-term changes

in HIV RNA and CD4 count levels

5. Liver fibrosis progression based on fibroscan, echo, biopsy and non invasive

blood test scores

6. A: Risk behaviour before and after acute HCV infection and/or HCV treatment

based on variables concerning sexual risk taking and drug use

B: Quality of life after acute HCV infection and before, during and after

HCV treatment

7. Further spread of HCV by sexual transmission and the impact of awareness,

early diagnosis and treatment on this (within mathematical models)

8. Level of clustering of HCV based on sequence data

9. Host genetic factors for susceptibility and outcome of acute HCV infection

# Study description

**Background summary**

In the Netherlands and other industrialized countries hepatitis C virus (HCV)
is emerging as a sexually transmitted infection (STI) among HIV infected men

who have sex with men (MSM). Case reports also describe sexual transmission of HCV in HIV negative MSM and HIV positive heterosexuals. HIV/HCV coinfection has been associated with accelerated progression to HCV, possibly HIV-related disease and less success in treatment of HCV. However, limited information is available on the sequelae of acute HCV infection in HIV infected individuals.

## Study objective

To study a cohort of HIV infected and HIV uninfected MSM and HIV infected heterosexuals who (subsequently) acquired HCV infection with a known date of HCV seroconversion:
1. To identify the frequency, clinical consequences and determinants (viral and host factors) of acquiring acute (primary, re- or super) HCV infection in HIV positive MSM, HIV negative MSM and HIV positive heterosexuals
2. To assess the outcome of HCV treatment following acute infection in HIV positive MSM, HIV negative MSM and HIV positive heterosexuals
3. To study the impact of acute HCV infection on the morbidity and mortality in HIV positive and HIV negative MSM and HIV positive heterosexuals
4. To study the role of HIV positive MSM who acquire acute HCV in the HIV epidemic among HIV negative MSM
5. To identify the driving factors of the HCV outbreak among MSM, in particular the role of HIV

## Study design

The study is open prospective observational cohort study. HIV positive MSM, HIV negative MSM and HIV positive heterosexuals with a (subsequently) acquired acute HCV infection will be asked by their HIV-specialist or hepatologist to join the study. Participant can be included at the time of acute HCV infection (prospective participants) or if they were diagnosed with acute HCV infection in the past (time of seroconversion must be known). To be able to study the first objective, per prospectively included HIV positive MSM with acute HCV, two controls per participant will be asked to join the study. Data collection mostly takes place during regular visits at either the HIV or hepatology outpatient clinic. The data
collected will mostly exist of data the specialist already collects for regular treatment or control. Extra data collection will exist of blood samples for virological, immunological and genetical study and questionnaires for study of (sexual) risk behaviour and quality of life. The follow-up of participants of this study will be for an -at the moment- indefinite period of time. The follow-up of control patients ends after two years.

## Study burden and risks

The majority of the data collection for this study will take place during regular visits at either the HIV- or hepatology outpatient clinic, and the

majority of data that will be collected for this study will comprise of data that are also collected for the regular care.

Participants with acute HCV: extra visits will take place:
- during the period in between time of inclusion and treatment, when a particpiant will not directly start treatment or will not start treatment at all. Participant wll be asked to give permission for extra blood sampling every four weeks during the first three months after inclusion.

Participants with acute HCV: extra data collected during regular visits:
- at 3 timepoints during the first period of 6-9 months after inclusion filling in a questionnaire concerning risk behaviour (prospective participants)
- at 3 timepoints during the first period of 6-9 months after inclusion filling in a questionnaire concerning quality of life (prospective participants)
- after the treatment period/first 6 months we will ask the participants in follow-up to fill in these questionnaires once a year
- during the regular visits in the treatment period their will be very regular blood samples taken to check on the effect oftreatment. We will ask participants their permission to take one to three extra tubes for the study during the regular venapunctions (10-35 ml blood)
- one fibroscan of the liver (in most patients all ready performed as standard of care)

Control patients: extra visits:
- no extra visits are necessary

Control patients: extra data collected during regular visits:
- 4 times during 2 years filling in a questionnaire concerning risk behaviour
- 4 times during 2 years filling in a questionnaire concerning quality of life
- during the regular visits regular blood samples will be taken. We will ask control participants their permission to take one to three extra tubes for the study during the regular venapunctions (10-35 ml blood) for 5 times in total
- one fibroscan of the liver

The participant will be asked to fill in these questionnaires during their visit at the clinic (max 20 min). When a participant will not be able to do this during the visit, he will be asked to fill in the questionnaires at home and to send these back to the researcher.

## Contacts

**Public**
Academisch Medisch Centrum

Nieuwe Achtergracht 100
Amsterdam 1018 WT
NL
**Scientific**
Academisch Medisch Centrum

Nieuwe Achtergracht 100
Amsterdam 1018 WT
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- male of female
- 18 years or older
- MSM or heterosexual
- HIV positive of HIV negative
- acute HCV infection
- written informed consent

## Exclusion criteria

- no follow-up of patient at an HIV or Hepatology outpatient clinic
- inability or unwillingness to provide informed consent or follow the requirements of the study

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-07-2015 |
| Enrollment: | 500 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 19-01-2015 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 29-06-2016 |
| 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 | NL48572.018.14 |