Hiv, hepatitis C and hepatitis B prevalence (and related risk behaviour) among detainees in Sittard, the Netherlands

Published: 23-10-2009
Last updated: 04-05-2024

To assess the prevalence of (recent) hiv infections, hepatitis B and C, and (related) risk behaviour among detainees in PI the Geerhorst, Southern Limburg in the Netherlands.

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

Summary

ID

NL-OMON32973

Source
ToetsingOnline

Brief title
Infectious diseases in detention, Sittard

Condition

- Viral infectious disorders

Synonym
hepatitis (jaundice), Hiv, infectious diseases

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hepatitis, Hiv, Prevalence, Prison

Outcome measures

Primary outcome

The primary outcome of interest is to assess the prevalence of viral infectious

diseases among detainees:

(Recent) HIV infections

Hepatitis B

Hepatitis C

Secondary outcome

Data collected in the questionnaires, concerning:

Demographics

Sexual behaviour

(Hard)drug use

Methadon use

History of detention

History of STD

Study description

Background summary

Previous Dutch cross-sectional sero-surveys in various cities among (injecting) drug-users (IDU) showed varying HIV prevalence (1-26%), hepatitis B (HBV) prevalence (35-68%) and hepatitis C (HCV) prevalence (35-74%). It is known that many drug users have been incarcerated at a point in time (in Rotterdam survey 88% of IDU, Heerlen 75%). International studies show high prevalence of infectious diseases in prison settings and high injecting drug use. Therefore,

penitentiary settings are an appropriate research setting to study infectious diseases among drug users and other detainees. Up till now, not much is known on infectious diseases in Dutch prisons. For that reason, the rationale of this study is to assess the prevalence of HIV, HBV and HCV among drug users and non-drug users in a prison setting in Sittard.

Surveillances of infectious diseases among high risk groups in the Netherlands is of importance for national monitoring. Results from this study may lead to design appropriate control measures to decrease further spread of infectious diseases and to decline the incidence of infectious disease on the long run. Furthermore results from surveys and studies among drug users will be reported to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in Lisbon by the Focal Point for Netherlands (Trimbosinstituut) for many years already. The results of this study will also be reported to the EMCDDA.

Study objective

To assess the prevalence of (recent) hiv infections, hepatitis B and C, and (related) risk behaviour among detainees in PI the Geerhorst, Southern Limburg in the Netherlands.

Study design

This study is a voluntary cross-sectional sero-prevalence study

Detainees will be thoroughly informed about the study and about the meaning and treatment possibilities of HIV, hepatitis B and hepatitis C. After this verbal explanation, an information leaflet will be handed out to all detainees. This will be done one week prior to the time that detainees will be approached to participate into the study. In order to participate, all participants need to sign the informed consent. This consent will also ascertain whether a person wants to receive the test results and whether the blood sample can be used for future investigations on virus transmission. Each participant will receive a telephone card of ¤ 10,- for his contribution to our study.
Participation includes a structured face-to-face interview, using a questionnaire, developed in different languages. The questionnaire contains approximately 70 questions and will take about 20 minutes. The questionnaire has been developed to collect data on risk factors (demographics, detention, sexual behaviour, hepatitis, STD (including hiv), (hard)drug use, and methadone use.
Finally, a blood sample will be taken by a nurse. This will be tested on hiv, hepatitis B en hepatitis C laboratory of the Erasmus MC in Rotterdam.

Study materials:

1) Questionnaire/interview

The questionnaire contains approximately 70 questions and will be administered by an interviewer from the RIVM. This interview will last around 20 minutes.
The questionnaires are coded using a study number. An independent researcher of the GGD Zuid-Limburg will be the only person who has access to the key of the study numbers.
Questionnaires have been developed based on equivalent preceding hiv surveys among drug users in different regions in the Netherlands (1994-1999) and therefore are validated. Moreover, subjects of questions from the questionnaire have been formulated by the UNAIDS/WHO for *second generation behavioural surveillance*. This indicates that the subjects have been designed specifically for hiv behavioural surveys among high risk groups. Finally, the questionnaire is outvoted with the Focal Point for Netherlands (Trimbosinstituut) and is compared with several European countries, which conduct similar hiv surveys among high risk groups (meeting EMCDDA). To conclude, the questionnaire will be tried out (as a pilot study) among 5 persons before starting the study definitively.

2) Blood sample
A venous blood sample will be taken by a nurse and will be tested on hiv, hepatitis B en hepatitis C in the laboratory in Rotterdam. In case a venous sample is not possible or desirable, a finger print will be used as an alternative.
Blood donation will be done by coding blood samples with a unique study number. Test results will only be given to participants who indicated in their informed consent that they wish to receive test results. As an independent researcher of the GGD Zuid-Limburg will be the only person accessing the key to link test results with personal data, he/she will provide test results to the medical services of PI the Geerhorst. If necessary, the medical services will subsequently provide treatment in accordance with the detainee.

Study burden and risks

Number of blood samples: 1
Number of interviews/questionnaires by researcher: 1
Number of visits medical services of PI the Geerhorst for test results (in case desired): 1

These are the minimum needed visits in order to perform this study as adequate as possible. We believe that in the light of the study burden, performance is nevertheless justified for all persons who will participate thanks to their possibilities to indicate whether they want to receive the test results or not, and which method for taking blood they prefer. Moreover, all participants will be included using a unique study number.

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

- Persons who stay at the departments A - E in PI the Geerhorst, Sittard
- Persons aged 18 and above
- Persons with a signed written informed consent for participating in the study

Exclusion criteria

- Persons without written informed consent
- Persons younger than 18 years old

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2010
Enrollment:	119
Type:	Actual

Ethics review

Approved WMO

Date:	23-10-2009
Application type:	First submission
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	NL28772.078.09