The Amsterdam Cohort Study (ACS) on HIV infection/AIDS, and other bloodborne and sexually transmitted diseases among drug users.

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To study the incidence and prevalence of HIV/AIDS and other bloodborne and sexually transmitted diseases and (HIV) related infections. To study the (natural) course, the (moleculair) epidemiology, pathogenesis and the effect of treatment and other...

| Ethical review | Approved WMO |
|-----------------------|------------------------|
| Status | Pending |
| Health condition type | Other condition |
| Study type | Observational invasive |

Summary

ID

NL-OMON32966

Source ToetsingOnline

Brief title

Amsterdam Cohort Study among drug users.

Condition

• Other condition

Synonym

nvt

Health condition

hiv/AIDS, bloedoverdraagbare en seksueel overdraagbare en (hiv) gerelateerde aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: GGD Amsterdam

Source(s) of monetary or material Support: De Amsterdam Cohort Studies worden financieel gesteund door het RIVM; de GGD Amsterdam; het Academisch Medisch Centrum Amsterdam; Sanquin en het universitair medisch centrum Utrecht

Intervention

Keyword: Amsterdam cohort study, Bloodborne and sexually transmitted disease, drug users, HIV/AIDS

Outcome measures

Primary outcome

HIV-infection, bloodborne and sexually transmitted diseases and (HIV) related

infections.

(Genetic) markers of HIV-infection, bloodborne and sexually transmitted

diseases and (HIV) related infections.

Secondary outcome

not applicable.

Study description

Background summary

Since 1985 the research department of the Municipal Health Service of Amsterdam focuses on research on HIV/AIDS, bloodborne and sexually transmitted diseases and (HIV) related infections in drug users. This protocol is admitted to broaden and replace all preceding protocols on this cohort of drug users previously approved by the Medical Ethics Board of the AMC and the MHS Amsterdam.

Study objective

To study the incidence and prevalence of HIV/AIDS and other bloodborne and sexually transmitted diseases and (HIV) related infections.

To study the (natural) course, the (moleculair) epidemiology, pathogenesis and the effect of treatment and other interventions in HIV infections and other

bloodborne and sexually transmitted diseases and (HIV) related infections. The riskfactors, including behaviour, for and spread of bloodborne and sexually transmitted disesases and HIV and (HIV) related infections.

Immunological and virological markers of bloodborne and sexually transmitted diseases and HIV and (HIV) related infections.

Genetic background of participants and the relation between genetic markers and sensitivity to viral infections and clinical course of infections.

Depending on future developments the number of infections studied can be extended.

Study design

Open, observational cohort study among drug users.

Study burden and risks

Participating in the ACS among drug users does not have any negative consequential risks for the participants, besides a possible small and transient bruise after venapuncture.

Once every 6 months questionnaires and blood samples are collected and depending on the research question physical examination and additional body tissue samples can be collected.

Contacts

Public GGD Amsterdam

Nieuwe Achtergracht 100 1018 WT Amsterdam NL **Scientific** GGD Amsterdam

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

drug users, living in the Netherlands, 18 years of age and older, signed Informed Consent, willing to fill out/answer questionnaires, willing to donate blood samples and other body tissue samples. Agreeing to be told results of medical tests.

Exclusion criteria

not relevant: if inclusion criteria are fullfilled, the person can join the ACS

Study design

Design

| Study type: Observational invasive | | |
|------------------------------------|-------------------------|--|
| Masking: | Open (masking not used) | |
| Control: | Uncontrolled | |
| Primary purpose: | Other | |

Recruitment

| NL | |
|---------------------------|------------|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-03-2009 |

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Enrollment:

Type:

550 Anticipated

Ethics review

Approved WMO Application type: Review commission:

First submission 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 CCMO ID NL27103.018.09