# HIDES * (HIV Indicator Diseases across Europe Study)

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Implement a survey initiative to assess HIV prevalence for one or more diseases and/or conditions within a specific segment of the population not yet diagnosed with HIV and that present for care with the specific disease/condition.

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

## Summary

### ID

NL-OMON36938

**Source**
ToetsingOnline

**Brief title**
HIV Indicator Diseases across Europe

### Condition

- Viral infectious disorders
- Peripheral neuropathies
- Cervix disorders (excl infections and inflammations)

**Synonym**
HIV prevalence

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** University of Copenhagen
**Source(s) of monetary or material Support:** Abbott,Boehringer Ingelheim,Bristol-Myers Squibb,Gilead Sciences,Tibotec Pharmaceuticals,University of Copenhagen

## Intervention

**Keyword:** Europe, HIV, Indicator diseases

## Outcome measures

### Primary outcome

How often does HIV occur (prevalence) in the diseases investigated.

### Secondary outcome

If person is found positive: patients characteristics like risk behaviour.

# Study description

### Background summary

Most patients infected with HIV across the European continent remain undiagnosed; although this percentage varies markedly from 15-80% across the continent. Undiagnosed HIV is harmful to the person infected as appropriate health interventions are then delayed until the HIV infection is diagnosed. It is also detrimental to society as persons unaware of their HIV infection may transmit more frequently to others than persons that are aware of their HIV status.

An important public health issue is hence how to diagnose more HIV-infected persons earlier in the course of their infection. In the US, the Centres for Disease Control and Prevention (CDC) have introduced testing guidelines where all persons are tested upon entry into the hospital system (the *opt-out* testing guidelines).

At the *HIV in Europe* conference held in November 2007, the general sense was that such an approach would not be suitable for Europe. Conversely, the conference recommended further development of focused HIV testing in patients presenting with certain clinical conditions and/or diseases (i.e. indicator condition guided testing).

Cost effectiveness analyses suggests cost savings if a population with a HIV prevalence of 1% or more are tested although this rate may be as low as 0.1%. However, there is very little * if any - evidence on HIV prevalence for various conditions and diseases in specific and easy to identify sections of society. This is true in general and particularly across the European continent.

## Study objective

Implement a survey initiative to assess HIV prevalence for one or more diseases and/or conditions within a specific segment of the population not yet diagnosed with HIV and that present for care with the specific disease/condition.

## Study design

The implementation will be conducted in two phases. Protocol version 1.0 implemented surveys in 8 diseases associated with high-risk behaviour or immune deficiency. Protocol version 1.1 will implement surveys of 11 diseases/conditions (listed below).

A. List of Indicator Diseases
The list of diseases below is not indicative of the most important indicator diseases for HIV but rather a list of diseases suggested for surveillance.

During protocol version 1.0, a total of 3588 patients were enrolled. Protocol version 1.1 will enrol patients presenting with the following diseases/conditions:

1. Presenting for care of malignant lymphoma, irrespective of type
2. Presenting for care of cervical or anal dysplasia or cancer, (Cervical CIN II and above)
3. Presenting for care of Hepatitis B or C virus infection (acute or chronic * and irrespective of time of diagnosis relative to time of survey),
4. Presenting with ongoing mononucleosis-like illness
5. Presenting with unexplained leukocytopenia or thrombocytopenia lasting at least 4 weeks
6. Presenting with seborrheic dermatitis / exanthema
7. Presenting with pneumonia, admitted to hospital for at least 24h
8. Presenting with unexplained lymphadenopathy
9. Presenting with peripheral neuropathy of unknown cause (diagnosed by neurologist)
10. Presenting with primary lung cancer
11. Presenting with severe or recalcitrant psoriasis (newly diagnosed)

For the Netherlands the selected diseases are cervical of anal dysplasia or cancer, Hepatitis B or C, peripheral neuropathy.
Persons with these illnesses will be approached to conduct an HIV test.
If bloodtests are already performed routinely, an HIV test will be done from the collected blood after the patient gave consent 24 hours later.
If no routine bloodtests are performed, a rapid HIV test will be done at the next visit after the patient gave consent.

If the HIV test turns out positive, specific care with follow up will be

offered.
Demografic characteristics will be collected. In case of a positive test, additional information will be collected.
Data storage will be performed anonimously.
The aim of the study is to collect data from at least 200 persons.

The general practitioner will be informed about the testresult.

### Study burden and risks

A rapid hiv test will be done. If the test is positive, a tube of blood will be taken from the patient. This can cause a haemorrhage.

## 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

1. Presenting for care of cervical or anal dysplasia or cancer, (Cervical CIN II and above)
2. Presenting for care of Hepatitis B or C virus infection (acute or chronic * and irrespective of time of diagnosis relative to time of survey
3. Presenting with peripheral neuropathy of unknown cause (diagnosed by neurologist
- HIV status unknown

### Exclusion criteria

HIV positive

## Study design

### Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 12-05-2013 |
| Enrollment: | 200 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 04-12-2012 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 | NL41999.100.12 |