

Screening for HIV, hepatitis B, Hepatitis C, syphilis and creatinine on self-collected dried blood spot samples*

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The objectives of this study are 1) To assess the sensitivity, specificity, positive and negative predictive values of HIV, HBV, HCV, syphilis and creatinine screening tests performed on dried blood client-collected samples at home, as compared to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON49756

Source

ToetsingOnline

Brief title

SPOT ON

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym

sexually transmitted infections, STI

Research involving

Human

Sponsors and support

Primary sponsor: GGD Amsterdam

Source(s) of monetary or material Support: GGD Amsterdam

Intervention

Keyword: Dried blood spot (DBS), Men who have sex with men (MSM), Sexually transmitted infection (STI)

Outcome measures

Primary outcome

The primary study endpoint is the sensitivity and specificity of syphilis and HIV screening tests performed on dried blood self-collected samples at home, as compared to these respective tests as performed on peripheral blood samples collected during an STI outpatient consult via vena-puncture.

Secondary outcome

- The sensitivity and specificity of HBV, HCV, and creatinine screening tests performed on dried blood self-collected samples at home, as compared to these respective tests as performed on peripheral blood samples collected during an STI outpatient consult via vena-puncture.
- The acceptability, feasibility and usability of dried blood self-collected samples at home.

Study description

Background summary

STI clinic guidelines recommend regular testing in men who have sex with men (MSM). However, the reality is that MSM are only partially tested, infrequently tested or not tested at all. The access time and capacity for clients visiting the STI outpatient clinic in Amsterdam is a recurring point of concern. With dried blood spot (DBS) self-sampling, a visit to the STI outpatient clinic may not be necessary. In addition to the service towards clients, this can also result in considerable cost savings for the clinic. The funds released can be used to increase the access time and capacity of clients with complaints, those who have been warned and those who need extensive counseling.

In this study we will assess the acceptability and feasibility of DBS in MSM visiting the STI clinic in Amsterdam. We will evaluate the performance of DBS for screening of HIV, HBV, HCV, syphilis and creatinine and compare these results to the serum tests collected during the STI consult.

Study objective

The objectives of this study are

- 1) To assess the sensitivity, specificity, positive and negative predictive values of HIV, HBV, HCV, syphilis and creatinine screening tests performed on dried blood client-collected samples at home, as compared to these respective tests as performed on peripheral blood samples collected during an STI outpatient consultation via vena-puncture.
- 2) To assess the acceptability, feasibility and usability of dried blood self-collected samples at home.

Study design

comparative study design to evaluate the performance of tests performed on client-collected DBS versus serum tests routinely performed on provider-collected samples

Study burden and risks

not applicable

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

- 18 years and older
- Being male and report to have had sex with a man in the past 6 months

Exclusion criteria

Having participated previously in this study.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 12-11-2020

Enrollment: 200

Type: Actual

Ethics review

Approved WMO	
Date:	21-02-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-11-2020
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	NL68213.018.18