Evaluation of measuring viral loads in self-sampled dried blood spots

Published: 31-08-2017
Last updated: 12-04-2024

The objectives of this study are: 1) To assess the user friendliness of the DBS self-sampling technique.2) To assess the quality of ssDBS.3) To estimate the agreement between viral loads in ssDBS and laboratory spotted DBS (labDBS).

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

Summary

ID

NL-OMON44163

Source
ToetsingOnline

Brief title
Measuring viral loads in self-sampled dried blood spots

Condition

- Viral infectious disorders

Synonym
infections caused by small micro-organisms, viral disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: DBS, evaluation, self-sampling, viral load

Outcome measures

Primary outcome

The main study parameters are:

* User friendliness

* Self-sampled DBS quality

* Viral loads

Secondary outcome

Not applicable

Study description

Background summary

As part of a larger project to stop the transmission of hepatitis C virus (HCV) among HIV positive men who have sex with men (MSM), we intend to develop a home-based HCV-RNA testing service, where dried blood spot (DBS) samples are collected at home and sent to our laboratory by regular post.

A home-collection test can only be implemented when people are capable of self-sampling a DBS at home of good enough quality. Therefore, in this study we aim to evaluate the self-sampling DBS technique for the detection of HCV RNA. The evaluation will include the assessment of user friendliness of the self-sampling technique and the quality of the self-sampled DBS (ssDBS). Furthermore, we will estimate the level of agreement between viral loads measured in ssDBS and in DBS spotted in the laboratory (labDBS).

To evaluate whether ssDBS performance depends on the target (viral pathogen), as in the future the testing service will be expanded to other viruses, we will also assess ssDBS for measuring human immunodeficiency virus (HIV) and hepatitis B virus (HBV) in this study.

Study objective

The objectives of this study are:
1) To assess the user friendliness of the DBS self-sampling technique.
2) To assess the quality of ssDBS.
3) To estimate the agreement between viral loads in ssDBS and laboratory spotted DBS (labDBS).

Study design

This study is a qualitative and quantitative study to to test the feasibility and evaluate the performance of DBS self-sampling for measuring viral loads.

Study burden and risks

Although drawing blood is a safe procedure, it can be uncomfortable and it may cause localised bruising. The participant may also feel some pain during the self-sampling of the DBS sample at home. The time investment from the participant is kept to a minimum by adding the recruitment visit onto a regular hospital visit so that no additional visits are required. Participants are not burdened by receiving a new diagnosis as they are already aware of their positive HCV, HIV or HBV status. The overall risks associated with participation are considered negligible and the burden minimal. All participants will be fully informed about the procedures and time investment requested.
For patients with an HCV infection, the development of a home testing service can be of benefit to screen for possible re-infections in the future if risk behaviour is not reduced.

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

* at least 18 years of age;
* speak Dutch;
* HCV, HIV or HBV viremic
* mentally competent;
* capable of understanding the study information, and
* provide written informed consent.

Exclusion criteria

* does not have a home address

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):	11-09-2017
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	31-08-2017
Application type:	First submission
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	NL62275.018.17