Validation of a novel capillairy bloodsampling kit (Demecal) for the detection of HIV antibodies

Published: 20-05-2008
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Technical validation of HIV antibody detection in capillairy blood sampled with the Demecal set.

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

Summary

ID

NL-OMON31729

Source
ToetsingOnline

Brief title
Home sampling of capillairy blood for HIV antibody detection

Condition

- Viral infectious disorders

Synonym
nvt

Research involving
Human

Sponsors and support

Primary sponsor: Demecal Europe BV (www.demecal.eu)
Source(s) of monetary or material Support: Demecal en Streeklab Haarlem (volledig uit eigen middelen)

Intervention

Keyword: Capillairy blood, Demecal, HIV, Homesampling

Outcome measures

Primary outcome

Measered HIV-antibody detection levels in capillairy plasma will be compared

with venous blood. Tests in both blood samples should be 100% comparable.

Secondary outcome

none

Study description

Background summary

There is a growing demand by epidemiologists as wel as individuals for home screening of HIV as part of sexual transmitted deseases. A new blood sampling device makes it possible to do home sampling of capillairy (fingerprick) blood and additionally sending tot a laboratory for analysis.

Study objective

Technical validation of HIV antibody detection in capillairy blood sampled with the Demecal set.

Study design

Twenty HIV positive patients visiting the HIV outpatient clinic for routine bloodsampling will be asked to participate in the study. Upon informed consent an extra tube of blood will be drawn during routine venous blood sampling subsequently a capillairy blood will be sampled by the Demecal devise. In the Demecal device cells and plasma will be separated. In the laboratory HIV antibodies will be maesured in the Demecal obtained plasme as well as the extra drawn venous blood sample. Both will compared by statistical analyses.

Study burden and risks

none

Contacts

Public
Demecal Europe BV (www.demecal.eu)

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Nederland
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Routine blood sampling requested for HIV positive patient.

Exclusion criteria

Younger than 18 years of age
No venal blood drawing possible

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):	10-12-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	20-05-2008
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	NL14310.029.07