Finger Prick blood collection validation studies

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Determine whether the finger prick blood collection procedure can reliably replace venepuncture blood collection for the following tests: PSA, Covid-19 serology, HbA1c and a series of standard and routine chemistry tests.

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

Summary

ID

NL-OMON51204

Source
ToetsingOnline

Brief title
Finger Prick blood collection validation studies

Condition

- Viral infectious disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Reproductive neoplasms male malignant and unspecified

Synonym
Covid-19 serology, general clinical chemistry, HbA1C, IVD Diagnostic tests: PSA

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Health Holland

Intervention

Keyword: Blood sample, diagnostic test, Home blood collections

Outcome measures

Primary outcome

Primary Objective:

- To determine whether the finger prick blood collection system procedure can reliably replace venepuncture blood collection for the PSA, Covid-19 serology, HbA1c and routine clinical chemistry testing.

Validation requirements:

- Correlation coefficient (Spearmans) of finger prick with venipuncture serum is > 0,90.

- Regression analysis: 95% CI of slope includes 1.00

- Less than 5% outliers (recovery < 70% or > 130%)

Secondary outcome

- Finger prick blood collection procedure performed by patients or healthy volunteers is feasible: > 80% of finger prick blood collection procedures performed results in a suitable sample for analysis.

Study description

Background summary

At the Netherlands Cancer Institute a home blood collection system was developed. This follow-up study aims do demonstrat that it can reliable replace the venipuncture procedure by a health care professional for a selection of

blood tests.

Study objective

Determine whether the finger prick blood collection procedure can reliably replace venepuncture blood collection for the following tests: PSA, Covid-19 serology, HbA1c and a series of standard and routine chemistry tests.

Study design

The study is designed to allow a pre-analytical method comparison between the standard venipuncture performed by a health care professional and a capillary blood sample collection using the developed by system by the patient or person him or herself for the PSA, Covid-19 serology, HbA1c and routine chemistry tests.

Study burden and risks

The study takes about 1 hour in which the participants need to perform a finger prick blood collection themselves using the developed system.
Participating healthy volunteers and health care professionals also undergo a venipuncture procedure.
Finally a questionaire is filled-in.

The fingerprik blood collection procedure might result in a sensitive finger and small bleedings afterwards.

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

Patients:
120x PSA requirest at blood collection facility
120x HbA1c request at blood collection facility

Healthy volunteers:
120X Proven Covid-19 infection health care professional
120X Partner of NKI patient (without Cancer)

Exclusion criteria

N.A.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-09-2021
Enrollment:	480
Type:	Actual

Medical products/devices used

Generic name:	Home blood collection system
Registration:	No

Ethics review

Approved WMO Date:	18-06-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	19-03-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL76225.031.20