Evaluation of microsampling systems for bloodanalysis in the follow-up of patients

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Effect of capillary blood collected in Hem-Col and kept at roomtemperature for 72 hrs on several routine laboratory parameters. The results of the tests are compared with the outcome of these tests when blood is collected by venapuncture and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49860

Source
ToetsingOnline

Brief title
Capillary blood sampling

Condition

- Other condition

Synonym
Preanalytical procudures for bloodsampling

Health condition

diagnostiek

Research involving
Human

Sponsors and support

Primary sponsor: Medlon b.v. Medische Diagnostiek
Source(s) of monetary or material Support: Medlon b.v.

Intervention

Keyword: Analysis, Capillary blood sampling, Self sampling

Outcome measures

Primary outcome

Effect of capillaire sampling in buffersolution and kept at roomtemperature on 23 laboratory parameters.In this study the outcome of different tests (CRP, ALAT, Albumine, Alkalisch fosfatase, Amylase, ASAT, Cholesterol, Kreatinine, Ferritine, Immunoglobulines, IJzer, Gamma-GT, HbA1c, HDL cholesterol, LDL Cholesterol, Apolipoproteine B, Totaal Eiwit, Transferrine, Triglycerides, TSH, Holotranscobalamine, Foliumzuur, Hemoglobin, Leucocytes, Trombocytes, LD and NT-proBNP) will be evaluated between blood drawn by venapuncture and capillary blood (capillary blood kept in Hem-Col tubes for 72 hrs).
Results of these tests (blood drawn by venapuncture) will be reported to their physician.

Secondary outcome

Participants experience of capillary sampling.

Study description

Background summary

New bloodcollection systems are nowadays on the market. Hem-Col is a new bloodcollectiontube which contains a buffer solution. A few drops of capillary blood can be stored in this buffer solution for 72 hrs at roomtemperature. This

system needs to be tested in a patientpopulation. In this study patients are asked to draw a few drops of capillary blood and put them in the buffer of absorbance material. The outcome of different laboratory parameters are compared to the outcome of the tests in venous blood and blood analysed within 4 hrs.
These new systems might have some advantages over the common practice:
Less blood is needed. 4-40 mL compared to maximal 200 uL.
Patients perform the bloodsampling themselves. No nurses are needed.
Patient can do the blooddrawing at home. They don't have to go to the nearest bloodcollectioncentre.
A independent scientific evaluation of these new systems has never been performed before.

Study objective

Effect of capillary blood collected in Hem-Col and kept at roomtemperature for 72 hrs on several routine laboratory parameters. The results of the tests are compared with the outcome of these tests when blood is collected by venapuncture and immediately analyzed.
The experience of the participants will be evaluated.

Study design

In total a group of 160 patients will be asked to participate in this study: 4 groups of 40 patients.
Group 1: venous sampling vs Hem-Col kept at roomtemperature for 72 hrs.
Group 2: venous sampling vs. Hem-Col kept at roomtemperature and mailed to the laboratory.

Study burden and risks

No burden or risk for the participants other than the normal burden and risks for capillary sampling by a CE marked lancet.

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 from the outpatient clinic
Aged above 18 years
Informed consent

Exclusion criteria

Unable to read and understand patientinformation.

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):	14-01-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-04-2020
Application type:	Amendment
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	NL70447.100.19

Study results

Date completed: 01-06-2024

Summary results
Trial ended prematurely