

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON49860

### Source

ToetsingOnline

### Brief title

Capillary blood sampling

### Condition

- Other condition

### Synonym

Preanalytical procedures 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 patient population. 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 µL compared to maximal 200 µL.

Patients perform the blood sampling themselves. No nurses are needed.

Patient can do the blood drawing at home. They don't have to go to the nearest blood collection centre.

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 room temperature 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 venipuncture 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 room temperature for 72 hrs.

Group 2: venous sampling vs. Hem-Col kept at room temperature 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**

### **Public**

Medlon b.v. Medische Diagnostiek

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NL

### **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

Patients from the outpatient clinic

Aged above 18 years

Informed consent

### Exclusion criteria

Unable to read and understand patient information.

## 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