Evaluation of new blood collection systems

Published: 18-09-2018
Last updated: 13-01-2025

The objective of the study is to determine the quality and usability of blood collection systems.

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

Summary

ID

NL-OMON48834

Source
ToetsingOnline

Brief title
Evaluation of new blood collection systems

Condition

- Other condition

Synonym
none

Health condition

geen enkele. De proefpersonen worden niet op aandoening geselecteerd.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bloodcollection tubes, Venous sampling

Outcome measures

Primary outcome

Comparison of labresults obtained with the regular collecting system or the new

one.

Secondary outcome

n.a.

Study description

Background summary

In order to perform adequate laboratory testing on bloodsamples, the quality of the blood collection systems (needles and tubes) are essential. Although much is know from literature, extra independent testing is sometimes necessary depending on het labtest. Medlon needs to verify the quality of the collection systems.

Study objective

The objective of the study is to determine the quality and usability of blood collection systems.

Study design

Healthy volunteers will be asked to take part of the study, which means two venapunctures. During this procedure a total amount of 43 ml of blood will be collected. The following tests will be done: HbA1, vitamin B1 and B6, PTH, ACTH, Methylmalonic Acid, PT, APTT, fibrinogen, PT-INR, Von Willebrand factor, Protein C, Protein S, Factor VIII, Factor IX, glucose, hs-Trop T, TSH, fT4, T3, anti-TPO, FSH, LH, hCG, cortisol, PSA, fPSA, CA 19.9, CA 15.3, AFP., CEA, CA125, S100b, Prolactin, Vitamin D, DHEAS, Tg, anti-Tg, Beta2 microglobulin, hGH, Testosteron, TSI, C-peptide, insulin, steroidprofiel. Results will be evaluated according to the CLSI evaluationprotocol number 9.

Also 68 patients attending our outpatient clinic for bloodcollection, will be

asked to participate in this study. During the regular venapuncture additionally 2 extra tubes will be collected. These tubes without a name, will be analysed for PT, PT-INR, Von Willebrand factor, Protein C, Protein S, Factor VIII, Factor IX, drugmetabolites or HIV viralload. Evaluation will take place according to the abovementioned protocol.

Study burden and risks

There is no extra burden or risk for participation than the only risk related to a regular venapuncture. It will take five minutes extra time for patients or healty volunteers.

Contacts

Public
Medlon b.v.

Koningsplein 1
Enschede 7512 KZ
NL
Scientific
Medlon b.v.

Koningsplein 1
Enschede 7512 KZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy volunteer or
patients attending the outpatient clinic

Exclusion criteria

patient with known anemia

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):	20-09-2018
Enrollment:	114
Type:	Actual

Ethics review

Approved WMO Date:	18-09-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-11-2019
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

ID: 20486
Source: NTR
Title:

In other registers

Register	ID
Other	29290
CCMO	NL66336.044.18
OMON	NL-OMON20486

Study results

Date completed:	01-07-2020
Actual enrolment:	110