Evaluation of blood collection systems

Published: 18-07-2018
Last updated: 13-01-2025

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20486

Source
NTR

Health condition

In this study the influence of the bloodcollectionsystem on laboratory results is studied on a number of specific laboratory tests.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Two collectionsystems (Greiner Bio-One and Becton Dickinson) are studied for specific laboratorytests. Results are evaluated in accordance to the CLSI Evaluation protocol number 9.

Secondary outcome

n.a.

Study description

Background summary

Rationale: The quality of the laboratory analyses performed to support either diagnostics or monitoring treatment of patients, is partly dependent of the quality of the blood collection system (needles) and the blood collection tubes used.
Objective: Comparison of laboratory analyses on plasma or serum obtained by different blood collection systems.
Study design: Comparative. Healthy volunteers will have blood drawn by two different blood collection systems (Vacuette® , Greiner BioOne and Vacutainer®, Becton Dickinson). Various types of additives will be included in order to perform a spectrum of laboratory analyses. Statistical evaluation will be performed using the CLSI EP-9 protocol.
Study population: Patients and healthy volunteers of 18 years and older.

Study design

n.a.

Intervention

Not applicable.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy volunteers aged over 18 years (40 subjects)
Patients using vitamin K antagonists (20 subjects), Patients on heparin therapy (20 subjects)
Patients with an decreased Von Willebrandfactor activity (5), protein C deficiency (5), protein S deficiency (5), Factor VIII deficiency (5) or factor IX deficiency (5).

Exclusion criteria

Patients having a decreased hemoglobin (Hb under 7.5 for women and Hb under 8.5 for men)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2018
Enrollment:	105
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48834
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7169
NTR-old	NTR7392
CCMO	NL66336.044.18
OMON	NL-OMON48834

Study results