Reference values in healthy volunteers

Published: 21-10-2020
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The main goal is to establish reference values of new clinical laboratory tests

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

Summary

ID

NL-OMON50133

Source
ToetsingOnline

Brief title
Reference values

Condition

- Other condition
- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
thrombosis bleeding

Health condition

Referentiewaarden

Research involving
Human

Sponsors and support

Primary sponsor: Diagnostica Stago S.A.S.
Source(s) of monetary or material Support: Door industrie

Intervention

Keyword: Hemostasis, Reference values, Thrombosis

Outcome measures

Primary outcome

The main study endpoints include the establishment of reference intervals for

new clinical laboratory tests in healthy volunteers

Secondary outcome

Not applicable

Study description

Background summary

Synapse Research Institute and the pharmaceutical laboratory, Diagnostica Stago S.A.S., which works in the in vitro diagnosis industry, wholly dedicated to the exploration of haemostasis and thrombosis developped several new assays and devices for studying haemostasis. Before these devices and assays can be used in practice in clinical laboratories, reference values in healthy volunteers need to be determined. In the future, these reference values will be supplied to customers as they are the most common decision support tool used for interpretation of clinical laboratory tests and thereby essential for patient care.

Study objective

The main goal is to establish reference values of new clinical laboratory tests

Study design

This study is an observational study in which blood will be drawn from healthy control volunteers by venapunction. Blood will be drawn from healthy volunteers (maximum 200/year) toestablish reference intervals of new clinical laboratory tests. This study will be conducted within 5 years.

Study burden and risks

Participation in this study involves drawing blood from healthy individuals by venipuncture. The burden and risks are minimal.

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

Healthy men and women >=18 and < 65 years old
Signed written consent to take part in the study

Exclusion criteria

Clinical pathology known to have links with coagulation disorders

Treatments likely to interfere with coagulation
Pregnant women or immediately post-partum (3 months)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-02-2021
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL73968.068.20