Predictors of Bleeding Evaluation in Adult Hematologic Patients with Bleeding Tendencies
Patients with established bleeding disorders: The BePa verification study

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To evaluate the diagnostic accuracy of the experimental tests to detect bleeding disorders and to evaluate whether or not they can be used for monitoring the effects of coagulant factor replacement therapy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON53063

Source
ToetsingOnline

Brief title
BePa study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Blood and lymphatic system disorders congenital

Synonym
hemorrhagic diathesis; bleeding disorder

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: "Blood Coagulation Disorders"[Mesh], "Diagnostic Tests, "Questionnaires"[Mesh], Routine"[Mesh]

Outcome measures

Primary outcome

Diagnostic parameters such as sensitivity, specificity, likelihood ratios and

AUC with 95% confidence intervals of the experimental haemostatic tests for

detection of a bleeding disorder.

Secondary outcome

Changes in experimental test results before and after prophylactic medication

within patients with bleeding disorders who receive prophylactic medication.

These changes will be compared to changes in plasma factor levels to evaluate

whether experimental tests can detect normalisation/increase of coagulant

factor levels.

Study description

Background summary

Accurate diagnosis of a bleeding disorder is mandatory for implementation of appropriate treatment. Lately, the market for haemostatic assays has been overflooded with
new commercially available tests, so-called global haemostatic tests, with unsupported
claims of predicting normal and abnormal haemostasis. Also the bleeding assessment tool
(BAT) might be useful as a diagnostic tool for detection of patients with a

possible bleeding
disorder. Benefits of these *experimental* tests and the BAT could be more accurate and
faster detection of bleeding disorders. The experimental tests could also improve
management of patients with bleeding disorders who use prophylactic medication. These
tests need validation in clinical practice.

Study objective

To evaluate the diagnostic accuracy of the experimental tests to detect bleeding disorders and to evaluate whether or not they can be used for monitoring the effects of coagulant factor replacement therapy.

Study design

In this diagnostic validation study we want to evaluate if the experimental tests and the bleeding assessment tool (BAT) are able to detect bleeding disorder. We will
evaluate these tests in patients with established bleeding disorders. The distribution of test
values from these patients will be compared with a distribution of reference values from a
healthy population without bleeding disorders, available from the PANE study (NL38767.068.11). Sensitivity and specificity of the experimental tests will be estimated at
various cut-off values and results will be summarized in receiver operating characteristic
(ROC) curves with corresponding area under the curve (AUC). Values of the experimental in
patients with a bleeding disorder before and after planned medical intervention will be used
to see if these tests are able to detect the differences in plasma factor levels before and after
treatment.

Study burden and risks

Future benefits of the new tests could be more accurate and faster detection of bleeding disorders and better management of patients with bleeding disorders who use prophylactic medication. However, the participants cannot benefit yet, because this study does not interfere with current clinical practice. The risks associated with participation in this study are low. A venapuncture is performed by skilled and experienced laboratory technicians. For the study, only a small amount of blood, 60-78 ml is needed. Therefore no harm can be

expected. Blood withdrawal could result in a hematoma, but this is usually not harmful. Bleedings from the blood withdrawal are usually negligible. In patients with prophylactic factor substitution the blood withdrawl will be planned in order not to interfere with their normal medication scedule.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debeyelaan 25
Maastricht 6202 AZ
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debeyelaan 25
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age => 18 years
Signed informed consent

Exclusion criteria

Pregnancy (or lactating);
Active bleeding due to medical interventions or surgical/obstetrical causes
Use of any interfering medicatie < 48 hours before laboratory testing
Known platelet level lower than 100,000/µl
Known hematocrit lower than 30%

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-10-2015
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	18-05-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	21-11-2022
Application type:	Amendment
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

ID: 29235
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51315.068.14