

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
<b>Study type</b>	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 flooded 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 withdrawal will be planned in order not to interfere with their normal medication schedule.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

Age  $\geq$  18 years  
Signed informed consent

### Exclusion criteria

Pregnancy (or lactating);  
Active bleeding due to medical interventions or surgical/obstetrical causes  
Use of any interfering medication < 48 hours before laboratory testing  
Known platelet level lower than 100,000/ $\mu$ l  
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: NTR

Title:

### In other registers

Register	ID
CCMO	NL51315.068.14