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

No registrations found.

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

Summary

ID

NL-OMON29235

Source
Nationaal Trial Register

Brief title
The BEPA study

Health condition

von Willebrand disease, platelet function disorders, coagulation factor deficiencies, fibrinolysis disorders, bleeding of unknown cause

Sponsors and support

Primary sponsor: MUMC+
Source(s) of monetary or material Support: not applicable

Intervention

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

Benefits of the new commercially available tests could be more accurate and faster detection of bleeding disorders and better management of patients with bleeding disorders who use prophylactic medication. These tests need validation in clinical practice. With this study we will evaluate the diagnostic accuracy of the experimental assays and the bleeding assessment tool (BAT) to detect bleeding disorders and to evaluate whether or not the experimental assays can be used to monitor the effects of coagulant factor replacement therapy. Also, this study will give us more insight in the haemostatic processes of patients with bleeding disorders.

Study design

2022 analysis of diagnostic parameters of Thrombin Generation for BUC patients

2022 analysis of diagnostic parameters of ROTEM for BUC patients
07.2021: cost effectiveness analysis of MUMC protocol vs new protocol for bleeding evaluation
2020 analysis of diagnostic parameters of flowcamber for PFA-only patients
2019 analysis of diagnostic parameters of multiplate, PFA and LTA for platelet function disorders
2019 analysis of diagnostic parameters of ISTH bleeding assessment tool for bleeding disorders

Contacts

Public
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Eligibility criteria

Inclusion criteria

Patients with established bleeding disorders (hemophilia A, B, other factor defects and VWD or platelet function defects) are recruited from the hemophilia treating centre ZON.
Age ≥ 18 years
Signed informed consent

Exclusion criteria

Pregnancy (or lactating)
Current active bleeding due to medical interventions or surgical/obstetric causes
Use of any interfering medication < 48 hours before laboratory testing
Known platelet level lower than 100,000/µl
Known hematocrite lower than 30%

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-07-2021
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53063
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9644
CCMO	NL51315.068.14
OMON	NL-OMON53063

Study results