Predictors of Bleeding Evaluation in Adult Hematologic Patients with Bleeding Tendencies

No registrations found.

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

Summary

ID

NL-OMON27868

Source
NTR

Brief title
The ProBE-AHP 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: Bayer bv for the first part of the study

Intervention

Outcome measures

Primary outcome

To assess the diagnostic parameters: sensitivity, specificity, negative predictive value, positive predictive value, likelihood ratio of the experimental haemostatic tests by comparing

them to our standard diagnostic algorithm (MUMC protocol) as gold standard.

Secondary outcome

Number of patients with discrepant results in different aggregations assays (multiplate vs. LTA);
Discrepant results between PFA and vWF antigen/activity;
Optimizing cost-effectiveness in diagnostic strategies.

Study description

Background summary

Observational study of consecutive patients stratified according to a clinical bleeding score in low, intermediate and high risk bleeding tendencies; subsequently undergoing laboratory testing. Experimental haemostatic tests will be compared to the standard diagnostic work-up for bleeding evaluation according to local hospital protocol to determine their value in diagnosing bleeding disorders. Ultimately, this study will contribute in establishing a clinical prediction guideline with a high-negative and high-positive prediction value.

Study objective

Newly developed blood assays need validation before widespread implementation in clinical practice in established bleeding disorders. We will compare the results of these tests to the results of our standard protocol to determine their diagnostic value. Ultimately, this study will contribute in establishing a clinical prediction guideline with a high-negative and high-positive prediction value.

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

Age > 18 years;
Signed informed consent;
Patients with (suspected) bleeding tendency.

Exclusion criteria

Pregnancy (or lactating);
Active bleeding due to medical interventions or surgical/obstetrical causes.
The use of medication which may interfere with diagnostic tests.

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:	300
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

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9643
Other	METC AzM/MUMC : METC144036

Study results