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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29235

Bron
NTR

Verkorte titel
The BEPA study

Aandoening

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

Ondersteuning

Primaire sponsor: MUMC+
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

MUMC+
Floor Heubel-Moenen

0433876543

Wetenschappelijk

MUMC+
Floor Heubel-Moenen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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%

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-07-2021
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 53063
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten