Version testing of EnzySystem Version A for Hemophilia A

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The primary objective of this study is to demonstrate that the EnzySystem HemA version A can record TG and quantify FVIII activity levels within a time frame of 60 min in fresh whole blood samples of healthy volunteers and patients with hemophilia A...

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

Summary

ID

NL-OMON56741

Source
ToetsingOnline

Brief title
HEMSTOL77 - EnzySystem

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
congenital bleedingdisorder, Hemophilia A

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: de Radboudumc spin off Enzyre B.V.,Enzyre B.V.

Intervention

Keyword: Diagnostic, Hemophilia A, point-of-care, Thrombin generation

Outcome measures

Primary outcome

Demonstrate that the EnzySystem HemA version A can record TG and quantitative FVIII activity levels within a time frame of 60 min in fresh blood samples of healthy volunteers and patients with hemophilia A.

Secondary outcome

Secondary study parameters are composed whether the measured values comply with the desired assay specificity and accuracy. Outcomes are analysed for equivalence compared to one-stage FVIII assay, FVIII chromogenic assay, thrombin generation via the Nijmegen Hemostasis Assay, and possibly via the Technoclone assay.

Is it possible to measure FVIII activity with the EnzySystem HemA version A in fresh blood samples of healthy volunteers and patients with hemophilia A, compared to the gold standard with;

- Precision in the normal range (60-140%): min. 30%
- Precision in the low range (3-10%): min. 50%
- Limit of Detection range min. 100 % FVIII activity
- Limit of Detection low range min. 3 % FVIII activity

Is it possible to measure TG with the EnzySystem HemA version A in fresh blood samples of healthy volunteers and patients with hemophilia A, compared to the

gold standard with;

- Precision in the normal range (60-140%) of control samples: min. 30%

- Precision in patient with hemophilia A: min. 50%

- Limit of Detection, high range > 400 nM thrombin activity

- Limit of Detection measured with Plasma, low range < 50 nM thrombin

other study parameters

All samples will also be tested for other hemostasis specific parameters as these parameters may affect a proper measurement of both FVIII activity and Thrombin Generation. The following parameters will be measured in plasma obtained from the whole blood vacutainers. Moreover, left over samples (plasma) will eventually be used to develop other coagulation related parameters.

- von Willebrand Factor antigen levels

- von Willebrand Factor ristocetin activity levels

- Prothrombin Fragment 1+2 levels

- ADAMTS13 activity

- FVIII antigen levels

- blood group

Study description

Background summary

To measure blood clotting, blood is taken from a vein. This blood is processed in the laboratory and then tested. A new device has been developed that requires only a very small volume of blood (5-10 drops of blood) to perform the laboratory tests. The long-term goal is that this device can be used by a

doctor or at home to quickly measure blood clotting. In this research we want to compare this new system with the standard methods - measurement in the laboratory - and evaluate whether the correct value is determined.

Study objective

The primary objective of this study is to demonstrate that the EnzySystem HemA version A can record TG and quantify FVIII activity levels within a time frame of 60 min in fresh whole blood samples of healthy volunteers and patients with hemophilia A in the Enzyre laboratory (for healthy volunteers) and the Radboudumc (for patients with hemophilia A).

Study design

This is a cross-sectional observational study.
All participants are asked to fill a questionnaire prior to blood collection.
The blood of healthy volunteers will be collected in an office of Enzyre BV, the blood of patients will be collected in the Radboudumc. Blood collection, by venepuncture, will be conducted by a Radboudumc research nurse or phycisian of the research team in both locations.
In total, four blood tubes with citrate as anticoagulant will be drawn (a total of around 11 mL).

Study burden and risks

We anticipate no risk or impact for the subjects and patients participating in the study. The protocol only refers to blood collection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy volunteers:
Age between 20between 20 to 70 years old (equally distributed over the age range)
- 7 volunteers 20-40 years old
- 7 volunteers 40-60 years old
- 6 volunteers 60+ years old

Hemophilia A patients:
Diagnosed with mild (FVIII activity levels 5-40%), moderate (FVIII activity levels 1-5%) or severe hemophilia A (FVIII activity levels <1%)
Medication
- On demand treatment
- Washout of medication of at least 24 hours after treatment with short half life (SHL) replacement therapy
- Washout of medication of at least 72 hours after treatment with extended half life (EHL) replacement therapy
Age 20-70 years old

Exclusion criteria

A healthy volunteer who meets any of the following criteria will be excluded from participation in this study:
use of anticoagulants or platelet antagonists (aspirin or any TAR);
known allergy to stainless steel;
trauma or surgery within the last two weeks;
pregnancy;
use of:

- NSAIDs;
- antimicrobial medication;
- thyroid inhibitors; or SSRI*s.

A hemophilia A patient who meets any of the following criteria will be excluded from participation in this study:
use of anticoagulants or platelet antagonists (aspirin or any TAR);
known allergy to stainless steel;
trauma or surgery within the last two weeks;
a bleeding episode within the last two weeks;
clinical indication of liver cirrhosis (echographic indication, enlarged spleen, decreased platelet count);
pregnancy;
acquired FVIII inhibitors;
use of:
- NSAIDs;
- antimicrobial medication;
- thyroid inhibitors or SSRI*s;
- Emicizumab.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2024
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL82879.091.22