Validation TAP-100 blood collection device

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Before routinely starting collection of blood with these devices several objectives need to be addressed. A) Is there a difference in coagulation activation parameters between blood collected by venous phlebotomy, finger prick capillary blood and...

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

Summary

ID

NL-OMON48781

Source
ToetsingOnline

Brief title
TAP-100 blood collection device

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
blood coagulation disorders, Hemophilia

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. ,Door de EFRO subsidie

Intervention

Keyword: biomarker, blood, sampling

Outcome measures

Primary outcome

The following biomakers will be analyzed in the different samples.

A) Full length Tissue Factor antigen levels

B) Prothrombin F1+2

C) D-dimer

D) Factor VIII antigen and activity levels

Secondary outcome

Blood volume obtained

Time of collection

Reaction of skin and bruises etc.

Study description

Background summary

Blood collection is an important parameter in the determination of blood coagulation. Normally, venous phlebotomy is required for standard analysis. For point of care tests capillary blood is sufficient. Capillary blood can be collected by a standard finger prick but might not be ideal as it is not directly mixed with a proper anticoagulant. Seventh Sense Biosystems has developed the TAP blood collection device able to collect a small volume of capillary blood (100 µl) which is directly anticoagulated. This new system might be an interesting collection device for our miniaturized thrombin generation assay, an assay that is more sensitive than other currently available coagulation point of care tests.

Study objective

Before routinely starting collection of blood with these devices several objectives need to be addressed. A) Is there a difference in coagulation activation parameters between blood collected by venous phlebotomy, finger prick capillary blood and capillary blood collected with the TAP device. B) Which anticoagulants is best to use?; C) is the composition of the measured biomarkers the same in controls and patients with severe Hemophilia A?

Study design

We aim to collect blood of 50 adult volunteers and 10 adult patients with hemophilia A. Blood of each donor will be collected by: finger prick (2 locations per donor, 1 for each anticoagulant, 2 drops per incision), one venous puncture and at two upper arms blood collected with either the 7SBio 100 µl Li-Hep (TAP 100-C*) device or the same TAP device filled with another anticoagulant. We aim to recruit hemophilia A patients within the Hemophilia Treatment Center (HTC) Nijmegen-Eindhoven-Maastricht (NEM), preferably at location Radboudumc.

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 by three different methods.

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

Inclusion criteria for healthy subjects: 20 years or older, no known (co)morbidities.
Inclusion criteria patients: To have severe hemophilia A and 20 years or older.

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)
- pregnancy

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)
- 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, enlarged liver, decreased platelet count)

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2020
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	14-11-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	12-05-2020
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	NL63677.091.17