Innovative methodology: the developement of a micro-array flow device

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Primary objective:The main purpose of the study is to develop a new concept of micro-based flow devices to detect (i) a prethrombotic state, (ii) the efficacy of established and novel antithrombotic medication, (iii) insufficient hemostasis and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON47347

Source
ToetsingOnline

Brief title
TAPAS

Condition

- Other condition
- Embolism and thrombosis

Synonym
Thrombus formation

Health condition

plaatjesaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: H2020-TAPAS

Intervention

Keyword: Coagulation, Diagnostics, Flow chamber, Thrombus formation

Outcome measures

Primary outcome

The main study parameters are thrombus formation, coagulation and platelet activity in vitro under flow conditions. Based on varying conditions a suitable device for individual patient monitoring will be developed which will be sensitive for normal anti- platelet and anticoagulation medication.

Secondary outcome

Non applicable

Study description

Background summary

In the present study it is the goal to develop a micro- array base flow device while ccurrently available assays suffer from one more of the following shortcomings. This includes low detection power, lack of specificity for the disease, lack of detection sensitivity, high costs, long handling procedure and laboriousness. Also, many of the newly developed tests are too expensive to be applied in general practice (outside the research laboratory). These technical and feasibility limitations have no doubt hampered the diagnostic application in patients at risk. As a consequence, in spite of the vast knowledge of mechanisms implicated in thrombosis and bleeding, we still lack suitable tools to assess the disease state in an individual patient. It is therefore important to combine all available knowledge and technical expertise to develop a suitable diagnostic platform, where most or all of these limitations are overcome

Study objective

Primary objective:
The main purpose of the study is to develop a new concept of micro-based flow devices to detect (i) a prethrombotic state, (ii) the efficacy of established and novel antithrombotic medication, (iii) insufficient hemostasis and bleeding risk, or (iv) efficacy of treatment with platelets or coagulant factors in case of bleeding. This goal is achieved in a two-step approach: Phase 1: establishment of optimal experimental conditions; phase 2: determination of inter- and intra-subject variability of flow-dependent thrombus formation at optimized conditions.

Study design

This study is an invasive observational design. However, the impact on the subjects will be minimal. Blood will be drawn from healthy volunteers (male and female) between the ages of 18 and 65 years. They will be recruited from Maastricht University and Maastricht UMC+. Before blood collection an informed consent will be signed.
In the first phase of this study subjects will give blood at one time-point. In the second phase measurements will be performed at 3 different time points. In all cases, two tubes of 9 mL blood will be drawn for the flow experiments, while two other tubes of 9 mL blood are taken for control experiment for assessment of platelet and coagulation function (routine aggregation, signaling and flow cytometric determinations).

Study burden and risks

The venipunctures will be made by experienced coworkers. Nevertheless, blood sampling causes local bruising, and incidentally a hematoma can be formed. There will be no direct benefit of the subjects.

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 men and women aged 18-65

Exclusion criteria

The use of anti-platelet or anti-coagulant drugs

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2010
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	19-04-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-03-2018
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL31480.068.10