Verification of preoperative screening for bleeding tendency in patients that report bleeding symptoms

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The main object is to evaluate the validity of a diagnostic screening package for bleeding tendency consisting of point-of-care devices when compared with the gold standard for bleeding tendency diagnosis.Other objects which will be investigated are...

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

Summary

ID

NL-OMON40106

Source
ToetsingOnline

Brief title
PANE-study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Blood and lymphatic system disorders congenital
- Vascular haemorrhagic disorders

Synonym
hemorrhagic diathesis;bleeding tendency

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: "Blood Coagulation Disorders"[Mesh], "Diagnostic Tests, "Point-of-Care Systems"[Majr], "Questionnaires"[Mesh], Routine"[Mesh]

Outcome measures

Primary outcome

Diagnostic parameters, such as sensitivity and specificity of the new study package when compared to the gold standard package in bleeding tendency diagnosis.

Secondary outcome

The predictive value of a bleeding risk score for presence of a bleeding disorder (according to the gold standard package) expressed as the area under the curve (AUC) of the receiver operating characteristic (ROC) curve.

Sensitivity and specificity estimates at different cut-off points of the bleeding risk score and corresponding percentages of patients undergoing more elaborate screening.

Results of tests aimed at detection of bleeding disorders (study package, consisting of point-of-care tests and genetic tests, see par 4.4 in research protocol) and bleeding risk score. Determine reference values of these tests for a pre-operative group, using a control group.

Use of blood products during a follow-up of 30 months after surgery.

Study description

Background summary

Each year 15,000 patients are screened before surgery at the outpatient department of anesthesiology on bleeding tendency. A short bleeding questionnaire is being used to guide the anesthesiologist if a patient has a possible bleeding tendency or not: a negative questionnaire can safely be regarded as a true negative, but in the case of a positive questionnaire little guidance is at hand what to do next. Lengthy laboratory tests, which only test part of the coagulation cascade, are done, but give to little information on bleeding tendency.
New point-of-care devices and genetic tests are faster and give a more overview of the coagulation cascade. Using these tests in a screening scenario has not been researched yet.
A more elaborate questionnaire for bleeding tendency, in which a score can be computed, could possibly narrow down the false positives while maintaining the sensitivity from the short bleeding questionnaire now being used.
A control group of 120 pre-operative patients is added to make reference values for these tests and questionnaire in this specific group, in order to judge test results from our patients as 'normal' or 'abnormal'.

Study objective

The main object is to evaluate the validity of a diagnostic screening package for bleeding tendency consisting of point-of-care devices when compared with the gold standard for bleeding tendency diagnosis.

Other objects which will be investigated are:
- the development of a more efficient screening algorithm by use of a bleeding risk score in patients who have one or more positive answers in the current short questionnaire,
- describing the differences in the usages of both human and synthetic blood products between the patient groups from this study,
- the validity of alternative/experimental methods such as a genetic test package for diagnosis of bleeding tendency in patients with possible disorders of hemostasis.
- Determine reference values for the tests/questionnaire in the screenings algorithm for this pre-operative group.

Study design

This is a diagnostic study to estimate sensitivity, specificity, positive and negative predictive value of a new package of diagnostic tools consisting of point-of-care devices, ATP secretion analysis and DNA-analysis (study package)

when compared with the gold standard package. For this blood (57ml) needs to be withdrawn from an antecubital vene and a more elaborate bleeding questionnaire needs to be reviewed with the help of research personnel. This will be done in study patients and control group patients.

Study burden and risks

Burden and risk associated with participation
Subjects have to make a appointment of fastened blood withdrawal. The total research time is 30 minutes for one subject.
They are subjected to little risk. Blood withdrawal of 57ml will not endanger subjects.

Benefit
Subjects will receive a card with detailed results and the interpretation of the results. This card can be used as a future reference card elsewhere.

Possible disadvantage
Subjects that choose for feedback on the genetic testing can encounter consequences for future insurances and mortgages, if a gene mutation is found. Patients are well informed about these consequences, so they can make an informed choice about feedback on DNA testing.

Group relatedness
Group selection is based on the population of patients attending the outpatient department of anesthesiology. No other base population can be used for this study. This is also true for the control group, as new reference values need to be determined for each specific patient group.

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

Study group:
Adult subjects (at least 18 years of age) with planned elective surgery
Patient has provided informed consent
Subject has marked at least one question positively on the preoperative screening list for bleeding tendency;Control group:
Adult subjects (at least 18 years of age) with planned elective surgery
Patient has provided informed consent
Subject has marked no questions positively on the preoperative screening list for bleeding tendency
(Add to D2; these controls are 'healthy' in the sense 'no bleeding disorder')

Exclusion criteria

For both the study group and control group:
Incapacitated subjects
Subjects referred to the hematology department preoperatively for consultation
Known blood clotting disease (haemophilia, Von Willebrand disease or other)
Use of thrombocyte aggregation inhibitors, NSAID*s or anticoagulants (i.e. prohibited medication)
Known thrombocyte level lower than 150,000/µl
Known hematocrit lower than 35%

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:	Recruitment stopped
Start date (anticipated):	26-08-2013
Enrollment:	870
Type:	Actual

Ethics review

Approved WMO Date:	04-04-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-07-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-02-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-09-2014
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC 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

ID: 26413
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL38767.068.11
OMON	NL-OMON26413

Study results

Date completed:	30-06-2017
Actual enrolment:	439

Summary results
Trial ended prematurely