Preoperative evaluation of bleeding risk during surgery

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Patients that report bleeding symptoms on the preoperative questionnaire that anaesthesiologists use, might have an undiagnosed bleeding disorder and/or more peroperative blood loss than patients that do not report bleeding symptoms. Whether...

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

Samenvatting

ID

NL-OMON26413

Bron
Nationaal Trial Register

Verkorte titel
PANE (policlinic anaesthesiology, patients are recruited from here)

Aandoening

Undiagnosed bleeding disorders (niet gediagnosticeerde stollingsstoornissen)
Per operative blood loss (perioperatief bloedverlies)

Ondersteuning

Primaire sponsor: Main investigator:
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Overige ondersteuning: CTCM - MUMC (eerste geldstroom)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the validity of a diagnostic screening package for bleeding tendency consisting of point-of-care hemostatic tests and the ISTH-BAT, compared to the golden standard an haematologist currently uses for diagnosing bleeding disorders.

Toelichting onderzoek

Achtergrond van het onderzoek

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 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.

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 and describing the differences in the usages of blood products, hemoglobin drop and morbidity/mortality between the patients that report bleeding symptoms and patients that do not

Countries of recruitment:
The Netherlands, MUMC

Doel van het onderzoek

Patients that report bleeding symptoms on the preoperative questionnaire that anaesthesiologists use, might have an undiagnosed bleeding disorder and/or more peroperative blood loss than patients that do not report bleeding symptoms. Whether diagnostic tests or an elaborate bleeding questionnaire is necessary in these patients to diagnose a bleeding disorder is unknown. In this study we include these patients, perform hemostatic tests, use the ISTH-Bleeding Assessment Tool and monitor per and post operative blood loss, use of blood products and mortality. Ultimateley, we want to design an easy-to-use screening algorithm for anaesthesiologists, that can detect patients at risk of per operative bleeding, so that preoperative measures can be taken to minimise blood loss, use

of blood products and ultimately morbidity and mortality.

Onderzoeksopzet

Between visiting anaesthesiology department for preoperative screening and the operation (window of 2-6 weeks)

Onderzoeksproduct en/of interventie

Diagnostic trial

Every patient (700 in total) that is included undergoes the following:

Blood withdrawal 57 ml - hemostatic tests are performed.

Bleeding questionnaire (ISTH-BAT)
Undergoes surgery as planned, clinical endpoints (blood loss, use of blood products and mortality) will be measured.

Also active controls will be included (not yet MEC approved). 120 in total; they will undergo the same screening package as patients and the same clinical endpoints will be measured. The aim of this active control group is mainly to validate the screening package in the same base population.
A larger prospective control group will be followed only for clinical endpoints (not yet MEC approved)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult subjects (at least 18 years of age) with planned elective surgery in:

o Orthopedic surgery

o Gynecologic surgery

o General surgery

o Vascular surgery

o Oral and maxillofacial surgery

o Urologic surgery

o Ear nose and throat surgery

o Neurosurgery

o Trauma surgery

- Subject has marked at least one of the following questions positively (adapted from preoperative screening list):

35. Heeft u last (gehad) van:
- Lang nabloeden na trekken van tanden/kiezen of na operatie of bevalling?
(Did you suffer from (abnormally long) bleeding after pulling of theeth/molars, after surgery or after delivery?)

- spontane tandvleesbloedingen?

(spontaneous gum bleeds?)

- spontane grote blauwe plekken?

(spontaneous large hematomas?)

- spontane neusbloedingen?

(spontaneous nosebleeds?)

- nabloeden bij kleine wondjes (b.v. na het scheren)?

(bleeding after small wounds (for instance after shaving)?)

- Hevig bloedverlies tijdens de menstruatie?

(Severe blood loss during menstruation?)

- Zijn er bij familieleden problemen met de bloedstolling? (Anders dan door het gebruik van bloedverdunnende medicatie)

(Do you have any family relatives with blood clotting problems? (Not due to blood thinning medication))

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Incapacitated subjects

- Patients < 18 years of age

- Subjects referred to the hematology department preoperatively for consultation

- Positive answer on one of the following questions from the preoperative screening list

38. Heeft u hemofilie, de ziekte Von Willebrand of andere bloedstollingziekte? Zo ja, welke?

(Do you have haemophilia, Von Willebrand disease or another blood clotting disease? If so, which?)

- 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%

- Known bleeding disorder

- Pregnancy

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	20-08-2013
Aantal proefpersonen:	820
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-07-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40106
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3873
NTR-old	NTR4070
CCMO	NL38767.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40106

Resultaten

Samenvatting resultaten
N/A