Validation of Thromboelastograph system (TEG®) in critically ill children admitted in the Pediatric Intensive Care Unit (PICU)

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Validation of accuracy of TEG® in critically ill children in the PICU.

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

Summary

ID

NL-OMON30976

Source
ToetsingOnline

Brief title
PIMTEG

Condition

- Other condition

Synonym
clotting study / hemostatic study

Health condition

bloedstolling

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: kinder intensive care, Thromboelastograph system (TEG®), validation

Outcome measures

Primary outcome

Establishing intra- and inter observer variability of TEG® parameters (clotting time (r), clot kinetics (k and alfa angle) and clot strength (maximum amplitude)) in 0,5 ml kaolin activated whole blood of critically ill children.

Secondary outcome

Determination of TEG® manipulation duration and time to results of the different TEG® parameters.

Study description

Background summary

Thromboelastography is a method to evaluate the viscoelastic properties during blood clot formation and clot lysis. The Tromboelastograph system (TEG®) is a point of care system using whole blood. TEG® is sensitive to all the interacting cellular and plasmatic components while conventional clotting tests measure plasma hemostasis only. Perioperative application of TEG® resulted in reduction of hemostatic products and tranfusions. Application of TEG® in postoperative and/or intensive care hemostasis management in critically ill children in the Pediatric Iintensive Care Unit (PICU) might improve diagnostic yield and thereby allowing more targeted therapy for complex hemostatic problems. Validation of TEG in this context using a sample volume of 0,5 ml whole blood has never been done.

Study objective

Validation of accuracy of TEG® in critically ill children in the PICU.

Study design

Non invasive prospective observational study.

Study burden and risks

Additional blood sampling from an arterial or central venous line will be combined with ordered blood samples for standard care implicating no additional risk or burden related to manipulation of the arterial or central venous line. Each TEG® sample is 0,5 ml whole blood and to compare two samples 1,0 ml of whole blood is needed. One participant can participate more than once but the total amount of blood drawn will be limited to 3 to 5 ml (depending on weight of the patient). In this patient group a total extra blood loss for sampling of 1 to 5 ml is regarded minimal compared to a mean weekly blood loss associated with regular blood sampling in pediatric intensive care. So the risk for participants related to additional blood loss due to sampling can be considered negligible. Because the hemostatic system in children is distinctly different from that in adults and the influence of critical illness on hemostasis is highly variable validation of TEG® can only be done in this patient group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

•Arterial or central venous line in situ. Insertion of arterial or venous line must be indicated on clinical basis as a part of normal critical care management. No lines will be inserted just for study purposes.
•Written informed consent

Exclusion criteria

•Dysfunctional arterial or central venous line - no free flowing sampling of blood possible

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	02-08-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL17681.042.07