I-chec - Identifying children with hereditary coagulation disorders

Published: 03-11-2016
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1. To evaluate the diagnostic accuracy of a newly developed pediatric BAT.2. To analyze the influence of age, sex and type of bleeding disorder on the total bleeding score and the score of individual bleeding items.

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

Summary

ID

NL-OMON47172

Source
ToetsingOnline

Brief title
I-chec

Condition

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

Synonym
coagulation disorder, Inherited bleeding disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Academisch Medisch Centrum;Novo Nordisk: acces to insight clinical research (unrestricted research grant),Novo Nordisk

Intervention

Keyword: Bleeding score, Children, Inherited bleeding disorder, Questionnaire

Outcome measures

Primary outcome

The main study outcome is the diagnostic accuracy of a newly developed pediatric BAT. This will be analysed by calculating the area under the Receiver operating characteristic curve (ROC) .

Secondary outcome

Linear regression will be used to model the association of bleeding score with age, sex and type of bleeding disorder in an multivariatble model

Study description

Background summary

The diagnosis of an inherited bleeding disorder is made based on the results from a patient*s family history, bleeding history and laboratory test results. Especially in children it may be difficult for the doctor to obtain a clear bleeding history, as bleeding symptoms can be subtle, children face less hemostatic challenges compared to adults and, for example, bruises in toddlers may be caused by normal activity. In order to standardize bleeding histories, bleeding assessment tools (BATs) have been developed, yielding a score based on the medical treatment history of the most severe bleeding episode for specific bleeding symptoms. Although it has been shown that high bleeding scores are associated with the presence of a bleeding disorder, the current pediatric BAT lacks sensitivity, efficiency and validity. The primary aim of the study is to develop a refined pediatric BAT that can be used as a screening tool for inherited bleeding disorders in tertiary clinics. The secondary aim of the study is to analyze the influence of age, sex and type of bleeding disorder on the total bleeding score and the score of individual bleeding items.

Study objective

1. To evaluate the diagnostic accuracy of a newly developed pediatric BAT.
2. To analyze the influence of age, sex and type of bleeding disorder on the

total bleeding score and the score of individual bleeding items.

Study design

This is a prospective cohort study. The cohort will include pediatric patients presenting with bleeding symptoms at 5 tertiary hematology clinics in The Netherlands, Canada and The United Kingdom. Data collection will last until the required amount of 200 patient inclusions has been reached. This is expected to take approximately 1 year.

Study burden and risks

Risks imposed by participation in this study are considered negligible.
Patients will undergo the same diagnosticprocedures/tests as usual (so, when they would not participate in this study).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. Age 0-18 years
2. Presenting with (1) the history, signs and symptoms of bleeding, and/or (2) abberant laboratory blood parameters and/or (3) a diagnosis of a bleeding disorder in relatives

Exclusion criteria

1. Patients with a previous diagnosis of an inherited bleeding disorder
2. Patients with a known, acquired cause of bleeding (ie. renal or liver disease, use of medication that is known to cause an increased bleeding tendency)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	03-11-2016

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 21443
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56790.018.16
OMON	NL-OMON21443