

identifying Children with Hereditary Coagulation Disorders (iCHEC): a protocol for a prospective cohort study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON21443

Source

Nationaal Trial Register

Brief title

iCHEC

Health condition

Bleeding symptoms

Bleeding disorders

Stollingsstoornissen

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The main study outcome is the diagnostic accuracy of the iCHEC BAT, as reflected by the

Area Under the Curve (AUC) of a Receiver Operating Characteristics (ROC) curve using results from the laboratory assessment as the reference standard

Secondary outcome

The secondary outcomes are the influence of age, sex and type of bleeding disorder on the total cumulative bleeding score and the score of individual bleeding items.

Study description

Background summary

Informatie niet aangeleverd door onderzoeker.

Study objective

We hypothesize that evaluation of the iCHEC bleeding questionnaire will result in a more accurate diagnostic screening tool for children who are suspected for a bleeding disorder

Study design

Not applicable

Intervention

Questionnaire

Lab

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Age 0-18 years, and
- History, signs or symptoms of bleeding, and/or
- Referred for evaluation of abnormal laboratory results of blood coagulation parameters, and/or
- Family member with an inherited bleeding disorder

Exclusion criteria

- Previous diagnosis of an inherited bleeding disorder
- Other, known, acquired cause of bleeding
- Unable to fill in the questionnaire

Study design

Design

Intervention model: Other

Masking: Open (masking not used)

Control: N/A , unknown

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 28-03-2017
Enrollment: 200
Type: Anticipated

Ethics review

Positive opinion
Date: 16-11-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47172
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5525
NTR-old	NTR7091
CCMO	NL56790.018.16
OMON	NL-OMON47172

Study results