Evaluation of a new vessel imaging system to support venous cannulation in children prior to elective, non-cardiac surgery in patients with a dark skin color.

No registrations found.

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

Summary

ID

NL-OMON23953

Source
NTR

Health condition

Infrared, Venous cannulation, Vessel visualization, Venipuncture

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)

Intervention

Outcome measures

Primary outcome

The main study parameter is success at first attempt (defined as the percentage of procedures in which the venous cannulation succeeded at the first attempt. An attempt is a penetration with a needle through the skin.)

Secondary outcome

1. Number of punctures;

2. Time to successful cannulation, if the procedure succeeded or not and if the VL was helpful or not. Timing starts at the moment the first attempt is made to search for a suitable vessel, by palpating or looking (with the system in use, looking with the system) and ends at the moment the line is flushed.

Study description

Background summary

A system (the VascuLuminator) was developed by our department of Medical Technology and Clinical Physics, that is able to visualize vessels underneath the skin. In this study, we test the effectivity of this system as an aid in venous cannulation in children prior to elective, non-cardiac surgery, by measuring number of punctures and duration of the procedure. The study takes place in a primary general hospital at Curacao in the Caribbean.

Study objective

To evaluate the usefulness of the VascuLuminator in children with a dark skin color that are obtaining a venous cannulation prior to elective non-cardiac surgery.

Study design

Measurements are made by an independend investigator. There is no follow-up of patients required.

Intervention

The VascuLuminator is the investigational product in this study. It is able to non-invasively visualize blood vessels by means of near-infrared light.
The intervention consists of the use of the device by the pediatric anesthetist during the puncture. There will be no extra intervention on the patient, since the patient already is obtaining a puncture as part of their normal treatment.

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Eligibility criteria

Inclusion criteria

All consecutive patients aged less than 18 years, undergoing elective, non-cardiac surgery in a primary general hospital at Curacao in the Caribbean will be included in the present trial.

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	110
Type:	Anticipated

Ethics review

Positive opinion Date:	05-09-2011
Application type:	First submission

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
NTR-new	NL2910
NTR-old	NTR3056
Other	METC UMC Utrecht : 09-312/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A