Supporting intravenous cannulation in children with infrared light; A clinical evaluation of three systems.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27576

Source
NTR

Health condition

Vessel visualization, Venipuncture, VascuLuminator, Infuus, Venous cannulation, Accuvein, Veinviewer, succes rate

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

To evaluate the effectivity of three different devices developed to visualize blood vessels with light, in intravenous cannulation in children.

Secondary outcome

To investigate if the devices are able to visualize blood vessels in the study population.

Study description

Background summary

In this study, we investigate three devices based on near-infrared light to visualize blood vessels, compared to a control group. Study population consists of children scheduled for elective surgery, obtaining an intravenous cannulation. Main outcome is success rate at first attempt.

Study objective

To evaluate the usefulness of three near-infrared based devices for intravenous cannulation in children prior to surgery.

Study design

Measurements are made by self-report at the moment the procedure is performed. There is no follow-up of patients required.

Intervention

The study consists of four arms: Three arms with one of the devices (the Accuvein, Veinviewer or the VascuLuminator) and one control arm with the standard procedure of intravenous cannulation. When one of the devices is allocated, it will be used during the procedure of intravenous cannulation. The study will be conducted as a pragmatic randomized trial. The operating room is the unit of randomization. Randomization will be performed by blinded envelopes, which will be opened by the investigator (NC) each day at 7.45 AM. The investigator will place the devices in the indicated operating room and provide CRF’s. One operating room will only receive a CRF and perform the procedure without device. Adaptive randomization will be used to guarantee that all three devices and the control group are equally divided among the different surgical specialties.

Contacts

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Eligibility criteria

Inclusion criteria

All consecutive patients aged less than 18 years, scheduled for elective surgery.

Exclusion criteria

Patients with a canula already in situ.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	12-01-2011
Enrollment:	1000
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL2541
NTR-old	NTR2659
Other	METC UMC Utrecht (amendement) : 09-312/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A