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

Gepubliceerd: 20-12-2010 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27576

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Mailstop C.01.230
P.O. Box 85500
Natascha Cuper
Utrecht 3508 GA
The Netherlands
+31(0)88 755 3243

Wetenschappelijk

Mailstop C.01.230
P.O. Box 85500
Natascha Cuper
Utrecht 3508 GA
The Netherlands
+31(0)88 755 3243

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with a canula already in situ.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	12-01-2011

Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2541
NTR-old	NTR2659
Ander register	METC UMC Utrecht (amendement) : 09-312/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A