Evaluation of a new vessel imaging system to support venous cannulation in children.

Gepubliceerd: 08-07-2009 Laatst bijgewerkt: 18-08-2022

To evaluate the usefulness of the VascuLuminator for venous cannulation in children.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27154

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

venous cannulation, venipuncture, near-infrared, vessel visualization, VascuLuminator.

Veneuze cannulatie, infuus, venapunctie, infrarood licht, vaat imaging, VascuLuminator

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: The study is funded by a ZonMW DO grant.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the percentage of procedures in which more than one puncture is required for successful venous cannulation or venipuncture (i.e. failure rate).

Toelichting onderzoek

Achtergrond van het onderzoek

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 that are difficult to puncture, by measuring number of punctures and duration of the procedure. The study takes place in the Netherlands.

Doel van het onderzoek

To evaluate the usefulness of the VascuLuminator for venous cannulation in children.

Onderzoeksopzet

Measurements are made by the nurses of the postoperative care unit at the moment the procedure is performed.
There is no follow-up of patients required.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All consecutive patients aged less than 18 years, referred to the pediatric anesthesiologist for venipuncuture or intravenous cannulation, will be included in the present trial.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

If a patient needs two cannulas placed at the same moment, the second puncture will be excluded (since the best place is already occupied with the first cannula).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2009
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-07-2009
Soort:	Eerste indiening

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	NL1791
NTR-old	NTR1901
Ander register	METC UMC Utrecht : 09-312/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A