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

Gepubliceerd: 08-04-2010 Laatst bijgewerkt: 18-08-2022

To evaluate the usefulness of the VascuLuminator for venipuncture for blood withdrawal in children and to find out for which type of patients the VascuLuminator is mainly used.

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

Samenvatting

ID

NL-OMON25144

Bron
Nationaal Trial Register

Aandoening

Vessel visualization, Venipuncture, VascuLuminator, bloedafname, bloedvaten, infrarood

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

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 or venipuncture (i.e. failure rate). A second main parameter is the number of patients in which the VascuLuminator is used during the weeks it is available.

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 and usability of this system as an aid in venipuncture in children referred to the phlebotomy station of a pediatric hospital. The study takes place in the Netherlands.

Doel van het onderzoek

To evaluate the usefulness of the VascuLuminator for venipuncture for blood withdrawal in children and to find out for which type of patients the VascuLuminator is mainly used.

Onderzoeksopzet

Measurements are made by the laboratory nurses themselves after 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 laboratory nurse 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.

The study is a pragmatic randomized trial with the week as unit of randomization, which implies that the VascuLuminator is available to use during a certain week or not, depending on randomization outcome. If it is available, the nurse can freely decide to use it or not on a patient. Results from patients of this group are compared to the control group, which consists of patients attending the phlebotomy station in the weeks the VascuLuminator is not available.

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, referred to the phlebotomy station of a pediatric university hospital for a blood withdrawal.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Blood withdrawals performed by a cappillary puncture instead of a venipuncture.

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:	26-04-2010
Aantal proefpersonen:	2000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-04-2010
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	NL2152
NTR-old	NTR2276
Ander register	METC UMC Utrecht : 09-312/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A