Reducing skinbreaking procedures in newborns

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The percentage of successful PIV insertions at the first attempt in newborns will increase with the Veinviewer® and/or Astodia®, two vascular imaging devices

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20449

Bron
NTR

Verkorte titel
PRIK project

Aandoening

newborns, skin-breaking procedures, attempts, insertion, Peripheral IV cannula (PIV) insertion

Ondersteuning

Primaire sponsor: Dept of Pediatrics, Division of Neonatology
Erasmus MC-Sophia Children's Hospital
Overige ondersteuning: Fonds NutsOhra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the percentage of procedures, which are successful in one attempt.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Peripheral IV cannula (PIV) insertion is a difficult and painful but inevitable procedure in hospitalized patients. The procedure is especially in neonates hampered by difficult visualization of blood vessels. Unfortunately, multiple puncture attempts are frequently necessary. To improve vessel puncturing in neonates, we compared three insertion methods.
Objective: The objective of this study is to evaluate the effectiveness of two vascular imaging devices in peripheral IV cannula insertion in neonates.

Study design: The study is a randomized controlled trial.

Study population: The study population will consist of 321 neonates admitted to the neonatal ward of the Erasmus MC-Sophia's children hospital in need of a PIV.
Intervention: Patients will be randomized to one of three methods. The PIV procedure will be performed with support of the VeinViewer® (intervention A) or the Astodia® (intervention B) or without support. The VeinViewer® and the Astodia® consist of a near-infrared light or LED, which is over or placed underneath the puncture site. In the control group PIV insertion will take place without guidance from the VeinViewer® or the Astodia® unless visualization is considered necessary. In that case a secondary randomization will be performed to select either intervention A or B. This group will be described separately from the study population.

Main study parameters/endpoints: The main study parameter is the percentage of procedures, which are successful in one attempt. The secondary study parameters will be the total number of punctures necessary for a PIV insertion and the duration of the insertion procedure.

Doel van het onderzoek

The percentage of successful PIV insertions at the first attempt in newborns will increase with the Veinviewer® and/or Astodia®, two vascular imaging devices

Onderzoeksopzet

Data collection will take place until 321 patients are included

Onderzoeksproduct en/of interventie

Patients will be randomized to one of three conditions during insertion of a peripheral infusion. The first time a newborn requires a peripheral intravenous cannula in the unit, randomisation will be performed to 1) with support of a device that helps to visualise the veins using infrared light (intervention A) or 2)with support of another device that visualises the veins using LED (intervention B) or without support using hands and eyes. In the control

group PIV insertion will take place without any device.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All consecutive newborns admitted to the NICU of the Erasmus MC-Sophia Children’s Hospital requiring a PIV in the first 2 weeks of life.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Newborns older than 2 weeks of age.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2013
Aantal proefpersonen:	321
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-06-2013
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	NL3871
NTR-old	NTR4039
Ander register	: 1203-029
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A