The impact of BD InstaFlash™ Needle Technology in Venflon™ Pro Safety needles on first attempt success rate of peripheral intravenous cannulation in adult patients, a double-blinded and randomized controlled trial

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

Samenvatting

ID

NL-OMON20431

Bron
Nationaal Trial Register

Verkorte titel
INSTAFLASH

Aandoening

Indication for peripheral intravenous cannulation, regardless the medical specialism or type of surgery they are admitted for.

Ondersteuning

Primaire sponsor: Catharina Ziekenhuis
Overige ondersteuning: Catharina Ziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is stated as the first attempt success rate of peripheral intravenous cannulation.

Toelichting onderzoek

Achtergrond van het onderzoek

Although advances have been made by recent research, focus seems mainly to be on the procedure of peripheral intravenous cannulation itself. Research on the impact of the peripheral intravenous catheter on the success rate is lacking, although innovations are made by manufactures of these medical products. Peripheral intravenous catheters are designed to gain access to peripheral veins of the patient's circulatory system. Correct placement of the catheter into the vein during the procedure of peripheral intravenous cannulation can be observed by blood in the notch of the catheter. Becton Dickinson (BD) Venflon™ products will incorporate the BD InstaFlash™ Needle Technology feature for faster visualization of flashback via a notch in the cannula. Faster visualization of this flashback of blood into the catheter in thought to increase first attempt success rate. The first attempt success rate of peripheral intravenous cannulation with the traditional needle (Venflon™ Pro Safety) was 81% in a previous study. A success rate of 90% on the first attempt is mentioned as clinically relevant and acceptable in clinical practice. We therefore hypothesize that the first attempt success rate of peripheral intravenous catheter placement will increase up to 90% in adult patients when a Venflon™ Pro Safety with BD InstaFlash™ Needle Technology is inserted, when compared to a Venflon™ Pro Safety without the BD InstaFlash™ Needle Technology.

Doel van het onderzoek

The hypothesis to be proved in this study project is: "first attempt success ratio of peripheral intravenous catheter placement will increase up to 90% in adult patients when a Venflon™ Pro Safety with BD InstaFlash™ Needle Technology is inserted, when compared to a Venflon™ Pro Safety without the BD InstaFlash™ Needle Technology".

Onderzoeksopzet

The study will be performed in two study groups. In patients in the intervention group, a Venflon™ Pro Safety with the BD InstaFlash™ Needle Technology will be inserted. In patients in the control group, a Venflon™ Pro Safety without the BD InstaFlash™ Needle Technology

will be inserted. Treatment in both study groups is equal, only the inserted catheter differs between both groups. Registrations of data upon the procedure of peripheral intravenous cannulation will be performed after inserting the catheter successfully.

Onderzoeksproduct en/of interventie

A peripheral intravenous catheter is a small hollow catheter that is advanced over a needle into a peripheral vein through the skin. There are four consecutive stages for peripheral intravenous cannulation, namely: (1) insertion of over-the-needle cannula into the vein, (2) confirming blood flow into the device, (3) advancing the cannula, and (4) saline flushing or starting the intravenous administration of fluids. Nurse anesthetists, who are familiar with the study protocol, routinely obtain the peripheral intravenous access. A peripheral intravenous catheter will be inserted in the upper extremity, and veins on the dorsal and ventral surfaces of the upper extremity are considered for peripheral cannulation, including the metacarpal, cephalic, basilic, and median veins. Intravenous cannulation was performed according to practice guidelines. The size of the inserted intravenous catheters ranged between 14 to 22 gauge, whereas the size of the catheter depended on the clinical situation. After each puncture, the practitioner checked whether the attempt was successful or not. The traditional landmark technique was applied. Before cannulation, a tourniquet was secured around the chosen arm, at least ten centimeters proximal to the elbow crease, and palpated and visualized to identify and acceptable vein. The tourniquet was tightened while maintaining pulsations of the radial artery. The puncture side was prepped with Chlorhexidine 70%. We define an attempt as one percutaneous needle puncture, regardless the amount of subcutaneous exploration from the single puncture site. After a failed attempt, a new attempt will be stated as any change in localizing a vein, followed by a new percutaneous puncture. Peripheral intravenous cannulation will be defined successful, if blood returns in the catheter and/or when a saline flush could be injected without compromising the vein and signs of subcutaneous injection were absent, and if the practitioner was able to inject a saline flush without signs of infiltration.
Investigational product/treatment: In patients in the intervention group, a Venflon™ Pro Safety with the BD InstaFlash™ Needle Technology will be inserted. In patients in the control group, a Venflon™ Pro Safety without the BD InstaFlash™ Needle Technology will be inserted. Treatment in both study groups is equal, only the inserted catheter differs between both groups. Following figure shows a Venflon™ Pro Safety with the BD InstaFlash™ Needle Technology, which is inserted in the needle. Treatment in both study groups is equal. Every surgical patient, admitted to the theatre complex, gets an intravenous catheter inserted. The procedure of peripheral intravenous cannulation does not differ between both study groups, except for the needle. The only difference between the intervention and control group is the needle that is used during the venous puncture, the rest of the device is comparable for both study groups. Nonetheless, after successful peripheral intravenous cannulation and according to the guidelines will the needle be removed after cannulation and will only the catheter be left in the patient. This catheter is equal for both types of products and the final device that will be left in the patient is identical.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria: subjects must be in the age of 18 years or older; subjects must be conscious and be able to adequately answer questions.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study: when an intravenous catheter is already inserted on the ward; are unwilling or unable to provide consent to participate; do not understand questions or generate adequate data, due to physical or communicational disorders.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	660
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-05-2019
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	NL7753
Ander register	MEC-U : W19.102

Resultaten