First attempt success ratio of intravenous cannulation with the Veinplicity®

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44449

Source
ToetsingOnline

Brief title
Veinplicity

Condition

- Other condition
- Therapeutic and nontherapeutic effects (excl toxicity)

Synonym
Difficult intravenous access / (peripheral) intravenous cannulation

Health condition

intraveneuze toegang, perifeer

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharina Ziekenhuis;Eindhoven;Nederland. Materialen (Veinplicity®) worden ten behoeve van dit onderzoek kosteloos vertrekt door Physeon GmbH. ,Physeon GmbH. (Zwitserland)

Intervention

Keyword: Difficult access (peripheral, Intravenous catheterization (peripheral), intravenous)

Outcome measures

Primary outcome

The primary outcome is the first attempt success ratio of peripheral intravenous catheter placement with the use of the Veinplicity® device, when compared to the traditional landmark technique, in patients with a medium-risk profile according to the A-DIVA scale. The outcome of interest is to reach a success ratio of 90% upon inserting a peripheral intravenous catheter by using the Veinplicity® device, in patients with a medium-risk profile according to the A-DIVA scale.

Secondary outcome

As secondary objectives, we are interested in the effects on:

* The time needed for intravenous cannulation;

* Patients satisfaction;

* Pain score upon intravenous cannulation;

* Practitioners satisfaction;

* The relation between the success ratio and patients demographics (age, sex, length, weight, skin color, dominant side, A-DIVA score, medical history and comorbidities);

* The relation between the success ratio and procedure related data (size of

the vein, size of the inserted catheter, side of cannulation, site of

cannulation).

Study description

Background summary

The Veinplicity® device (Physeon, Schaffhausen, Switzerland) is an electrical stimulation device, which can be used as an adjunct for peripheral intravenous cannulation. It is said to increase local intravascular blood volume and therefor improves a practitioners* ability to gain intravenous access. Because of this statement, we hypothesize that the first attempt success ratio of peripheral intravenous cannulation will be increased in patients with a medium-risk profile according to the A-DIVA scale, with the use of the Veinplicity® device, when compared to the traditional landmark technique.

Study objective

The primary outcome is the first attempt success ratio of peripheral intravenous catheter placement with the use of the Veinplicity®, when compared to the traditional landmark technique, in patients with a medium-risk profile according to the A-DIVA scale.

Study design

This is an observational intervention study. The results of the procedure in the intervention group, first attempt success ratio upon peripheral intravenous cannulation in spite of using the Veinplicity® device, will be compared to a historical control group.

Intervention

Patients included in the current study, even get a peripheral intravenous catheter inserted. In the intervention cohort, the target vein will not be dilated with using a tourniquet, but by using the Veinplicity® device, which is an electrical stimulation device that can be used as an adjunct for peripheral intravenous cannulation.

Study burden and risks

Major complications of a failed attempt of inserting a peripheral intravenous catheter are related to the delay of diagnoses and treatment, arterial punctures, hematomas, paresthesia, or the risk of central venous catheterization after multiple unsuccessful attempt of peripheral intravenous cannulation. The use of the Veinplicity® device will for itself not reduce the risk for this complications, however the risk for complications will be reduced when the success ratio increases. Using the Veinplicity® device does not expose patients to additional risks, besides those which can occur during every intravenous puncture. This study will involve subjects who either has experienced difficultly with venous access being gained in the past or are likely to. It is expected that the device will benefit these patients and others in the future with more first time cannulation success, less time spent obtaining access, greater patient and clinician satisfaction, reducing the need for more invasive types of cannulation (central venous cannulation), reducing the stress that failed cannulation can bring to both the patient and clinician.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
* Patients must be in the age of 18 years or older;
* Patients with a medium risk profile on the A-DIVA scale (score 2 or 3);
* Patients must be conscious and be able to adequately answer questions.

Exclusion criteria

A potential patient who meets any of the following criteria will be excluded from participation in this study:
* Patients in which an intravenous catheter is already inserted on the ward;
* Patients with medical devices in the body (pacemaker, ICD, trans-cerebral electrode placement, electrode placement that applies current to the carotid sinus region, other neurostimulators);
* Patients who do not understand questions or generate adequate data, due to physical or communicational disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2018
Enrollment:	125
Type:	Actual

Medical products/devices used

Generic name:	Veinplicity®
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-12-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24775
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61818.100.17
OMON	NL-OMON24775
OMON	NL-OMON25489