A multicenter, first-in-human study to investigate a venipuncture device prototype and assess its safety and feasibility

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON47958

Source
ToetsingOnline

Brief title
Feasibility of a venipuncture device prototype

Condition

- Other condition

Synonym
blood drawing, venipuncture

Health condition

de venapunctie

Research involving

Human

Sponsors and support

Primary sponsor: Vitestro B.V.
Source(s) of monetary or material Support: Sponsor/verrichter

Intervention

Keyword: Automation, Image recognition, Robotics, Venipuncture

Outcome measures

Primary outcome

Feasibility: Number of successful automated venipunctures

Safety: number of adverse events and number of adverse device events

Secondary outcome

Subject's pain experience

Duration of device procedure in seconds

Causes of missed venipuncture

Study description

Background summary

Venipuncture is one of the most common invasive medical procedures in the world. Although the analysis of blood samples and post-analytical validation has been fully automated, the actual collection of blood remains a manual process. Missed punctures is a potential cause of complications. Furthermore, manual venipuncture is an important cause of laboratory errors and incurs high costs. Automation of venipuncture offers an intriguing opportunity for improving patient outcome while reducing operational costs. Vitestro has developed a prototype of a venipuncture device (VDPA) that will be tested in this feasibility study. This clinical investigation presents the first step towards a fully autonomous venipuncture device.

Study objective

The primary objective is to investigate feasibility (number of successful automated venipunctures) and safety (number of adverse events and adverse device events). Secondary objectives are to determine subject's pain experience, duration of device procedureand causes of missed venipuncture.

Study design

A feasibility study, non-randomised. Subjects will have one venipuncture with the venipuncture device prototype A (VDPA)

Intervention

Automated venipuncture by the VDPA in one arm

Study burden and risks

The burden for subjects consist of a one-time visit to the hospital blood drawing department, during which subjects undergo an automated venipuncture in 1 arm. Afterwards, subjects will answer questions. Risks of the device are those associated with manual venipuncture, most important complications are hematoma and vasovagal syncope. Several control measures were taken to prevent risks: de depth of needle insertion is limited, the prototype will only insert a needle in case of adequate 3D reconstruction of ultrasound images, the identified puncture location is verified by research phlebotomist.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age *18 years.
* Written signed informed consent must be obtained.
* Able to participate in this study

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Unable to follow instructions.
* Previous chemotherapy or intravenous drug use
* Diseases that are associated with poor vein conditions, such as hemophilia
* Coagulation disorders or use of anticoagulants
* Contra-indications for venipuncture in the cubital fossa (e.g. due to local skin disease, burns, edema, hematoma, previous lymph node extirpation, an arteriovenous fistula, or a paretic/ paralyzed arm)
* Recurrent vasovagal reactions during venipuncture
* Tattoos in the cubital fossa

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	82
Type:	Anticipated

Medical products/devices used

Generic name:	Venipuncture Device Prototype A
Registration:	No

Ethics review

Approved WMO

Date:	16-05-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL69427.015.19