Autonomous Blood Drawing Optimization and Performance Testing

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This study has several objectives, in different (subsequent) study phases:• A1. Optimize and validate the technology of the VD to reach non-inferiority• B1. Demonstrate non-inferior performance and safety of the VD, for CE marking• B2. Demonstrate…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53917

Source
ToetsingOnline

Brief title
ADOPT
Autonomous Blood Drawing

Condition

- Other condition

Synonym
Venous blood drawing

Health condition

veneuze bloedafname

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AI, Automation, Robotics, Venipuncture

Outcome measures

Primary outcome

The primary endpoint:

- First-time venipuncture success rate.

Secondary outcome

Secondary endpoints:

- Rate of punctured participants

- Rate of hemolyzed samples (>0.5 g/l)

- Adverse events.

Study description

Background summary

The venipuncture procedure is one of the most common invasive medical procedures in the world. There is a shortage of healthcare personnel, which limits blood drawing capacity, reducing access and availability of care. This is of particular importance during pandemics.
Vitestro has spent five years developing an autonomous blood drawing device, the VD. The VD can draw a blood sample using state of the art intelligent technology and robotics. With the VD, for the first time, an invasive patient procedure can be performed autonomously. A prototype has been tested clinically in the BRAVE Study in >1,000 participants in four different sites. The ADOPT Study builds on the results and learnings from the BRAVE Study.

Study objective

This study has several objectives, in different (subsequent) study phases:
• A1. Optimize and validate the technology of the VD to reach non-inferiority
• B1. Demonstrate non-inferior performance and safety of the VD, for CE marking
• B2. Demonstrate analytical performance for clinical implementation
• C1. Optimize and further validate the technology of the VD to reach equivalence
• C2. Implement and optimize the VD in the real-use setting, to reach equivalence
• 0. Non-invasive VD testing for miscellaneous technology improvement.

Study design

Study design:
Prospective interventional study, open label.
Phase A: exploratory.
Phase B1: confirmatory
Phase B2: exploratory
Phase C1 and Phase C2: exploratory.
Phase 0: exploratory

Design: non-inferiority (only phase B1).
Control group: manual venipuncture (only phase B2).

Intervention

An automated venipuncture with the VD-1

Study burden and risks

The burden for participants consist of one or two venipunctures, 5-20 minutes in total. The risks are considered comparable to manual venipuncture.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >=16 years.

Exclusion criteria

• Unable to follow instructions, due to mental disability and/or incapacity
• Unable to use device correctly due to physical impairment or disability (for example a patient with severe contractures or deformities)
• No venipuncture possible in cubital fossa of both arms (for example: after amputation of both arms)
• No venipuncture possible in cubital fossa due to contra-indications in both arms (for example: tattoos in both arms)
• Incapacitated persons
• Pregnant or breast-feeding

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2023
Enrollment:	13618
Type:	Actual

Medical products/devices used

Generic name:	Venipuncture Device
Registration:	No

Ethics review

Approved WMO Date:	08-07-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-04-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	11-12-2024
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL80965.000.22