JBZ Atellica VTLi BNP,NT-proBNP en D-Dimeer sample comparison study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON51277

Source
ToetsingOnline

Brief title
Atellica VTLi sample comparison study

Condition

- Heart failures
- Embolism and thrombosis

Synonym
Heart failure; Venous thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Siemens Healthineers Nederland B.V./Point of Care Business
Source(s) of monetary or material Support: Door Siemens Healthineers B.V.;Nederland

Intervention

Keyword: Heart failure, Point of care, Reagent cartridge, venous thromboembolism

Outcome measures

Primary outcome

The primary outcome consists of the regression parameters (including slope and associated 95% confidence interval) of a regression analysis of the measurement results of the Atellica VTLi System. The regression used for this will be the Passing-Bablok method or other regression method recommended by CLSI EP09c. The regression parameters will be calculated for the combinations of sample types, as follows:

• Venous whole blood / capillary

• Venous whole blood / venous plasma

• Capillary / Venous Plasma

This analysis will be performed for all three analytes (BNP, NT-proBNP and D-dimer), thus resulting in 9 regressions. The correlation coefficient will also be determined for each of the 9 data sets.

In addition, the bias in Bland-Altman plots of samples above the limit of quantification (LoQ) will be determined for the different pairs of samples.

Secondary outcome

The secondary outcome is a graph and bias determination of the differences between venous whole blood and plasma measurements, using a Bland-Altman analysis. Hematocrit (x-axis) will be plotted against the percent difference between whole blood and plasma results (y-axis). Analysis by regression will determine the possible bias and maximum hematocrit value.

Analysis of data from the method comparison study will consist of the above regression parameters based on Passing-Bablok analysis and an associated correlation coefficient for each analyte, comparing the measurement results on reference equipment (x-axis) with the measurement results on the Atellica VTLi System (y-axis).

Study description

Background summary

The Atellica VTLi BNP/NT-proBNP/D-Dimer Test System is a portable test system for in vitro diagnostic use in the quantitative measurement of B-type natriuretic peptide (BNP), N-Terminal pro B-type natriuretic peptide (NT-proBNP) and/or D-dimer in fresh human capillary (fingerstick) whole blood, venous whole blood or plasma using the Atellica VTLi Immunoassay Analyzer. This test system is intended for point of care (POC) and central laboratory use and consists of a dedicated reagent test cartridge, analyzer and associated docking station and service software. The BNP and NT-proBNP tests can be used as an aid in the diagnosis of heart failure and as an aid in assessing the severity of heart failure (HF). The D-dimer test can be used as an aid in the diagnosis of deep vein thrombosis and pulmonary embolism.

For the development of this new method, it is necessary to establish that the results in different sample types (venous whole blood, plasma and capillary) are equivalent. This information is currently not available as the system has just been developed, and is now being validated and verified. Promising results have been found from previous (pre)clinical studies with a different test configuration, with good correlations between the different sample types for the 3 analytes.

Study objective

Primary objective of the study is to compare the readings of the different sample types (venous whole blood, plasma and capillary) for the three different analytes (BNP / NT-proBNP / D-dimer) on the Atellica VTLi system, according to CLSI EP09c guidelines.
Secondary Objective is to analyze blood-plasma differences as a function of hematocrit (Hct) values.

Frozen plasma samples will also be used for a method comparison study with

reference equipment; hereby the measurement results of the Atellica VTLi test system in plasma will be compared with measurement results on reference equipment for the three analytes, according to CLSI-EP09c guidelines.

Study design

In this study, the concentrations of BNP, NT-proBNP and D-dimer are measured in capillary, venous whole blood and plasma samples with the Atellica VTLi test system. Patients who meet the inclusion and exclusion criteria will be approached for participation. There is no intervention other than taking a finger prick and extra blood tubes.

The BNP and NT-proBNP venous whole blood and plasma tests will be performed with blood from an EDTA collection tube, the D-dimer venous whole blood and plasma tests will be performed with blood from the citrate collection tube.

Study burden and risks

The patient undergoes a finger prick, during which it is possible that a slight pain in the finger is experienced for a very short time (about 1 minute). In addition, with a venous blood sample (which usually takes place routinely), two tubes of blood (<4 mL) are taken. Therefore, the burden of participation is very low and the risk involved in participating in the study is negligible. On the other hand, exactly this patient population would benefit from accurate and rapid diagnostics for BNP, NT-proBNP and D-dimer at the point of care, i.e. the product that can be developed through these study.

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>/= 22 year; and
Patients with suspected or diagnosed heart failure, deep vein thrombosis and/or pulmonary embolism; and
Competent patients who have given consent and signed for participation.

Exclusion criteria

Age< 22 year; or
Patients with cognitive impairment or inability to understand study information; or
Patients who are unwilling or unable to give written consent; or
Patients previously enrolled in this study; or

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-09-2022
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Atellica VTLi High Sensitve Troponin-I test system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-10-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL81329.000.22