Atellica VTLi Sample matrix study for Plasma Separation Membrane Comparison

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Compare Atellica VTLi reference plasma separation membrane with at least one alternative plasma separation membrane using hs-cTnI values from capillary whole blood from fingerstick, Li-Hep whole blood and plasma from venipuncture.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON51710

Source
ToetsingOnline

Brief title
Atellica VTLi Plasma separation Membrane Comparison

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
heart attack, Myocardial Infarction

Research involving
Human

Sponsors and support

Primary sponsor: Siemens Healthineers
Source(s) of monetary or material Support: bedrijven

Intervention

Keyword: Atellica VTLi, Plasma separation membrane

Outcome measures

Primary outcome

The differences between the filters will be analysed using Passing-Bablok regression, according to CLSI EP09c from the Clinical and Laboratory Standards Institute. The parameter to be assessed is the significance of the Passing-Bablok regression, which is performed for each different sample type. Additionally, for each sample type, the measurement results of the filters should demonstrate a correlation coefficient (R) of at least 0.95

Furthermore, the venous whole blood and plasma results as a function of hematocrit for the alternative filter(s) will be analyzed.

Secondary outcome

not applicable

Study description

Background summary

The Atellica VTLi Test System, including the analyzer, associated disposable single- use hs-cTnI Reagent Cartridges, docking station and service software, are already CE marked IVD products. The Atellica VTLi hs-cTnI Reagent Ccartridge uses a filter membrane to separate the plasma and the blood cells. The CE marked cartridges use membranes of a single supplier/production location. Differences between suppliers and/or production locations can lead to variation in assay performance of the membranes.

This study is designed to compare membranes from different production locations

and/or manufacturers.

Study objective

Compare Atellica VTLi reference plasma separation membrane with at least one alternative plasma separation membrane using hs-cTnI values from capillary whole blood from fingerstick, Li-Hep whole blood and plasma from venipuncture.

Study design

This study requires the following procedures to be conducted: at least 50 patients will be included, with cTnI concentrations distributed over the measurement range. A maximum of 100 patients will be included to fill the desired ranges. Part of the testing will be done near the bedside of the patient and part will be done at the central laboratory.

For each patient, the following sample sources will be collected:

• Capillary whole blood from fingerstick with an uncoated transfer device
• Li-Hep venous whole blood
• Li-Hep venous plasma (generated from the Li-Hep venous whole blood)

One (1) replicate needs to be tested for the capillary samples per plasma separation membrane. A maximum of 2 finger sticks per patient will be performed. Two (2) replicates need to be tested per membrane per patient for both venous plasma and venous whole blood samples.
The time at which each sample is obtained and tested will be recorded.

Subjects will be selected for hs-cTnI concentrations across the measurement range.
The number of sample sets in the different ranges are targeted at:
• >=15 sample sets 2-40 ng/L, of which at least 5 around the medical decision point: 16-40 ng/L
• >=8 sample sets 41-200 ng/L
• >=8 sample sets 201-1250 ng/L
Hematocrit (Hct) values will be obtained from the Laboratorium Information system.
The Atellica VTLi hs-cTnI test results must not be used for patient diagnosis or treatment, and are for study purposes only.

Study burden and risks

This is a low risk IVD study. All blood samples will be collected using standard blood collection techniques used for venipuncture and fingerstick. Most of the patients will have an indwelling cannula from which blood samples are drawn. In some cases an additional venipuncture is required to be performed

as part of this study. The fingerstick sample, taken only for study purposes, may result in a small pain at the side of the fingertip, but this pain is usually of short duration and tolerated very well.

Troponin tests available on central lab-systems carry the burden of associated logistics to get a sample to the lab and the result reported back to the physician, which significantly impacts the time to a disposition decision. Point-of-care (POC) assays have the potential to shorten this turn-around time, enabling more rapid decision making. Using this specific POC analyzer, biomarker results can be obtained within 10 minutes, aiding in the early diagnosis of Myocardial Infarction (MI).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- >=22 years old
- Patients presenting at the coronary care unit with suspected/diagnosed ACS

and thus having suspected elevated cTnI values
• Patients willing and able to sign informed consent form

Exclusion criteria

• Patients younger than 22 years
• Patients requiring emergency treatment
• Patients with cognitive impairment or inability to understand study information
• Patients previously enrolled in this study
• Pregnant or breastfeeding women

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):	01-06-2022
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Atellica VTLi High Sensitivity Troponin-I Test System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-09-2022

Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-09-2022
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-09-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-10-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-10-2022
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	06-10-2022
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Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL81218.075.22