Atellica VTLi sepsis biomarker sample comparison study

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Primary Objective: Compare Atellica VTLi Sepsis biomarker values from capillary whole blood from fingerstick with anticoagulated whole blood and plasma from venipuncture.Secondary Objectives: Correlate the blood and plasma outcomes on the Atellica…

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON51331

Source
ToetsingOnline

Brief title
Atellica VTLi sepsis biomarker study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
infectious diseases, sepis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atellica VTLi, sepsis

Outcome measures

Primary outcome

To compare Atellica VTLi Sepsis values from capillary whole blood to anticoagulated whole blood and plasma from venipuncture.

Secondary outcome

To correlate the blood and plasma outcomes on the Atellica VTLi Sepsis tests to the corresponding biomarker levels measured on the routine analyzers in the laboratory. Also, to evaluate results of the sepsis tests as function of hematocrit (Hct) values.

Study description

Background summary

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection caused by bacterial, viral, and fungal pathogens.

Sepsis is very time-sensitive and can rapidly progress to organ failure and death, every hour of delay in treatment can increase mortality by 7% (Kumar, 2006). Using this POC IVD analyzer, results for key sepsis biomarkers can be obtained in as little as 10 minutes from a venipuncture or fingerstick. Compared to the longer waiting time and higher volumes necessary to receive similar results from hospital laboratories, this Investigational Device can aid in the rapid diagnosis of sepsis, resulting in potentially significant patient benefit for those who suffer from this life-threatening disease.

Apart from blood derived biomarkers, other vital parameters make the diagnosis sepsis more/less likely. These parameters are included in scores, such as the SIRS Criteria or the qSOFA criteria.

Data collected in this clinical study is primarily intended to derive sample

equivalence information in the development phase of the Sepsis tests.

Study objective

Primary Objective:
Compare Atellica VTLi Sepsis biomarker values from capillary whole blood from fingerstick with anticoagulated whole blood and plasma from venipuncture.

Secondary Objectives:
Correlate the blood and plasma outcomes on the Atellica VTLi Sepsis tests as function of the currently used assay platforms.
Correlate the blood and plasma outcomes on the Atellica VTLi Sepsis test as function of the corresponding hematocrit (Hct) values.

The purpose of the Atellica VTLi Sepsis Biomarker study is to evaluate the equivalence between the different sample types for testing Sepsis blood biomarkers on the Atellica VTLi system according to CLSI EP09c.

Study design

This is an In Vitro Diagnostic Observational Study.
Capillary whole blood samples from fingerstick, anticoagulated venous whole blood and anticoagulated venous plasma samples will be collected at the Catharina hospital emergency/ICU department. Up to 150 valid sample biomarker results, covering the entire measuring range for the different sepsis analytes, will be collected in each matrix claimed (i.e. venous whole blood and plasma and capillary blood). More patients might be screened to fill the desired concentration ranges. We aim at an equal distribution of biomarker levels. Patients sample matrix types need to be collected as matched sets for this study. Per patient set, a single lot of each cartridge type will be used. Multiple cartridge configurations may be tested to cover multiple sepsis biomarkers. Part of testing will be done near the bedside of the patient and part will be done at the local laboratory.

Per patient, the following sample sources are collected:
• Capillary whole blood with an uncoated transfer device
• Anticoagulated venous whole blood
• Anticoagulated venous plasma

The time that the blood is taken and tested will be recorded for each sample.

Samples will be collected across the measurement range for the different biomarkers, targeted at 1/3th in the low range, 1/3th in the intermediate range and 1/3th in the high range.

When a certain range is completed, the sample collection can continue until the

required ranges are filled. Including more samples in the ranges that are already completed is acceptable and expected.

All Sepsis biomarker results from the different sample types within the measuring range will be recorded and used for data analysis. In case of no or *invalid* results, retesting will be performed, if sample volume allows. No and invalid results will be reported.

For this study no personal data will be collected, other than for screening of the in- and exclusion criteria. The Atellica VTLi Sepsis test results will not be used for patient diagnosis or treatment, but only for study purposes.

Hematocrit values will be obtained from the medical record (or measured in Li-Heparin venous tube). If available, also sepsis biomarker levels will be obtained from the laboratory data.

Left-over plasma from samples will be aliquoted, stored and transferred to Siemens Eindhoven for additional biomarker assay analysis

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. Some of the patients will have an indwelling cannula from which blood samples are drawn. In most 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.

Potential benefits of the Sepsis test include increased survival rates in septic patients due to earlier detection, but also reduction of unnecessary antibiotic use in patients with low levels of biomarkers due to early result reporting. Sepsis is a very time-sensitive, life-threatening disease in where every hour of delay in treatment can increase mortality by 7% (Kumar, 2006). Using this POC analyzer, biomarker results can be obtained within 10 minutes, aiding in the early diagnosis of sepsis.

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

• Patients >= 18 years old
• Patients presenting at the hospital with suspected/ diagnosed infectious disease
• Patients able and willing to provide written informed consent

Exclusion criteria

• Patients younger than 18 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):	01-11-2022
Enrollment:	150
Type:	Anticipated

Medical products/devices used

Generic name:	Atellica VTLi sepsis test system
Registration:	No

Ethics review

Approved WMO

Date:	28-02-2023
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

No registrations found.

In other registers

Register	ID
CCMO	NL81494.000.22