The use of a blood transfer device to improve venous blood gas analysis

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

Summary

ID

NL-OMON56903

Source
ToetsingOnline

Brief title
Venous blood gas analysis

Condition

- Other condition

Synonym
Venous bloodgas

Health condition

patiënten voor wie een bloedgasanalyse is geïndiceerd

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood collection, Preanalysis, Venepuncture, Venous bloodgas

Outcome measures

Primary outcome

The primary aim of this study is to optimize VBG sampling, by testing the accuracy of VBG results obtained through the use of a blood transfer device (BTD). We will evaluate a comprehensive set of blood gas results (pH, bicarbonate, pCO2, pO2, oxygen saturation, lactate, ionised calcium, sodium, chloride, potassium, haemoglobin, FCOHb, FMethHb) from a VBG samples collected via a BTD.

We will compare VBG results collected in three different tubes methods by using the same blood draw from an IV line:

1) directly into a blood gas syringe (golden standard referred to as blood gas syringe)

2) into a heparin tube and subsequently transferred to a capillary (referred to as capillary VBG)

3) Into a dummy tube and subsequently transferred to a blood gas syringe via a BTD (referred to as adapter VBG).

Secondary outcome

1. Evaluate influence of a different tube sequence: according to the CLSI and

NVKC, tubes should be drawn in a specific sequence as the sequence may influence results. According to this guideline, a VBG should be drawn first in the sequence. However, it would be more practical to take a VBG at the end. We will test whether taking a VBG at the end of the sequence would influence blood gas results.

2. Following the sequence, a conventional VBG is immediately drawn in a blood gas syringe, but it can also be taken from a heparinized tube and then transferred to a blood gas syringe. It is not clear what the effect of heparin is on blood gas results, wherefore it is currently taken in a tube without anticoagulation (dummy tube). However, the use of a heparinized tube will minimize the risk for in vitro blood clotting, that can interfere with results.

3. The effect of storage (room temperature or on ice), time-to analysis and transport (pneumatic tube) have not been adequately described.

Study description

Background summary

Blood gas analyses are crucial in the assessment of critically ill patients, especially in emergency and intensive care settings. Traditionally, the gold standard for these analyses has been arterial blood gas sampling (ABG). However, ABG sampling is associated with an invasive, painful, and technically challenging procedure that requires skilled phlebotomists. Increasingly, venous blood sampling (VBG) as an alternative for blood gas analysis is gaining popularity. VBG is obtained through venipuncture, a standard method of blood collection that can be performed by any trained personnel. Previous research has demonstrated that VBG sampling is a reliable alternative, showing a strong correlation between venous and arterial pH as well as bicarbonate levels.

The use of a VBG facilitates that samples can be collected during routine venipuncture and enables nurses, rather than laboratory staff, to perform the collection at the department. However, this approach also entails specific pre-analytic variables, such as exposure to environmental air, transport time, or collection method, e.g. samples taken through a peripheral intravenous line (IV) or using a blood transfer device (BTD).

Study objective

The primary objective of this study is to investigate the accuracy of a BTD on blood collection tubes. This prevents air exposure wherefore all the available blood gas results (pH, bicarbonate, pCO2, pO2, oxygen saturation, lactate, ionised calcium, sodium, chloride, potassium, haemoglobin, FCOHb, FMethHb) should be similar as a VBG from a central venous line. It will be evaluated whether this will reduce pre-analytic errors, can improve workflow, and will be cost-effective.

Study design

Hospitalized patients will be asked to participate in this study. During the regular venipuncture, a maximum of 30 mL additional blood will be collected. We will collect blood directly in a blood gas syringe (syringe VBG), in a heparine tube for transfer to a capillary (capillary VBG), and in a dummy tube transferred with a blood transfer device to a blood gas syringe (adapter VBG). These samples will be analysed with a bloodgas analyzer. If the adapter VBG produces accurate results as compared to the syringe VBG, we will test various pre-analytical variables as described in secondary objectives.

We will collaborate with medical doctors who requested a blood gas analysis for these patients. The medical doctor will order a laboratory test and will inquire whether the patient wants to participate in the study. These patients include subjects on the first aid and intensive care who are competent to adequate answer questions.

Blood will be drawn by qualified and experienced personnel, and patients will be asked to give informed consent, after reading and discussing all the relevant information and their questions. Previous experiences have shown that patients are highly motivated to participate in research studies that will improve diagnostics and health.

This study consists of two parts. The main purpose of this study is to perform a method comparison between the capillary VBG and an adapter VBG. Results will be obtained by our regular blood gas analyzer. For this, we will compare capillary VBG vs. syringe VBG results with adapter VBG vs. syringe VBG results. VBG will be collected using the same blood draw from an IV line. If results of the adapter VBG show a smaller bias, we can proceed with part two: optimizing

the workflow by testing various pre-analytic variables as described in the secondary objectives. Results will be compared with a syringe VBG.

Study burden and risks

Blood samples will be collected by qualified healthcare personnel. Drawing blood is a routine diagnostic procedure and will be conducted in compliance with the department's safety guidelines. The total amount of additional blood will be a maximum of 30 mL per subject and will be drawn from the same venipuncture made for diagnostic purposes. Although a needle puncture might cause a hematoma, no additional needle puncture is necessary, wherefore we consider this study at minimal risk for the patient.

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

Hospitalized patients patients who require a bloodgas analysis

Exclusion criteria

Patients younger than 18 years old and incompetent patients

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	186
Type:	Anticipated

Medical products/devices used

Generic name:	Blood Transfer Device
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	29-07-2024

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	NL86451.100.24