Blood Gas Comparison trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27674

Source
NTR

Brief title
BGC trial

Health condition

Respiratory complaints

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Zuyderland Medical Centre

Intervention

Outcome measures

Primary outcome

The main study endpoint is the frequency of alterations in treatment of patients with respiratory complaints in the emergency department (ED) based on venous blood gas (VBG) results compared to treatment based on arterial blood gas (ABG) results. We will assess which alterations in treatment occur, the characteristics of alterations and which ABG resuls cause the change.

Secondary outcome

Secondary endpoints are the agreement between venous and arterial pH, bicarbonate, pCO2, lactate and pO2 and the correlation between venous and arterial pO2 and the peripheral oxygen saturation measured with pulse oximetry.

Study description

Background summary

An integral part of assessment of patients with respiratory complaints in the emergency department (ED) is determining the acid-base, ventilation and oxygenation status. Traditionally, arterial blood gas (ABG) results have been used. Previous research shows venous blood gas (VBG) results could be a reliable alternative. ABG sampling is often painful, can be challenging to perform, and carries greater risks. The primary objective of this study is to test the hypothesis that treatment of patients with resipratory complaints in the emergency department (ED) based on venous blood gas (VBG) results does not differ from treament based on arterial blood gas (ABG) results. We will assess the frequency of alterations in treatment bases on VBG results compared to treatment based on ABG results. Which alteration intreatment occur, the charesteristics of the alterations and the ABG results causing the change (pH, bicarbonate, pCO2, lactate or pO2) will be assessed.

Study objective

Treatment of patients with respiratory complaints in the emergency department (ED) based on venous blood gas (VBG) results does not differ from treatment based on arterial blood gas (ABG) results.

Study design

Total expected study duration is 6 weeks.

Intervention

One extra blood sample will be obtained with the standard venepuncture or from the peripheral venous catheter to collect the venous blood gas. No extra vascular puncture is required.

Contacts

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Eligibility criteria

Inclusion criteria

Patients (≥ 18 years) presenting in the ED with dyspoea, respiratory rate > 20/min or peripheral oxygen saturation <95%, a reliable saturation measured by pulse oximetry and an indication, determined by the treating physician, to determine the acid-bae, ventilation and oxygenation status by arterial blood gas.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Not capable to give informed consent within reasonable time after stabilisation and abating of the accompanying psychological stress, and no representative availabe to give informed consent on behalf of the patient.
- Arterial blood gas results are required for other reasons than determining the acid-base, ventilation and oxygenation status, such as determing the alveolar to arterial oxygen gradiënt (A-a gradient).
- No physician or qualified nurse available for ABG sampling.
- Failed ABG or VBG sampling after two attempts.
- Previous participation in the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2019
Enrollment:	155
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	15-10-2019
Application type:	First submission

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
NTR-new	NL8085
Other	METC Zuyd : METCZ20190084

Study results