

Comparison of peripheral venous and arterial blood gas in management of patients with respiratory complaints in the emergency department.

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

Summary

ID

NL-OMON48393

Source

ToetsingOnline

Brief title

Blood Gas Comparison trial (BGC trial)

Condition

- Other condition

Synonym

Respiratoiry complaints

Health condition

Respiratoire klachten veroorzaakt door verschillende onderliggende ziektebeelden

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Zuyderland (RvE Cap 1)

Intervention

Keyword: Blood gas, Emergency department, Respiratory complaints

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 results 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 the 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 (the reference standard) have been used. ABG sampling is often painful, can be challenging to perform, and carries risks.

Previous research shows venous blood gas (VBG) results are a reliable alternative with a good correlation between venous and arterial pH and

bicarbonate. Venous carbon dioxide partial pressure (pCO₂) and venous lactate can also be used as a reliable screening method for arterial hypercapnia and hyperlactatemia. In addition, the development and widespread use of pulse oximetry makes it easy to determine the oxygenation status of patients. Despite the evidence, arterial blood gas sampling remains the common method of determining acid-base, ventilation and oxygenation status in patients with respiratory complaints in the ED.

Study objective

The primary objective of this study is to test the hypothesis that 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. We will assess the frequency of alterations in treatment based on VBG results compared to treatment based on ABG results. Which alterations in treatment occur, the characteristics of the alterations and the ABG results causing the change (pH, bicarbonate, pCO₂, lactate or pO₂) will be assessed.

Study design

Prospective cohort study.

Study burden and risks

Patients will undergo venepuncture or peripheral venous catheter placement and arterial blood gas (ABG) sampling as part of standard care. One extra blood sample will be obtained with the standard venepuncture or from the peripheral venous catheter to collect the venous blood gas (VBG). No extra vascular puncture is required. Treatment is according to current guidelines.

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) presenting in the ED with dyspnoea, respiratory rate > 20/min or peripheral oxygen saturation < 95%, a reliable saturation measured by pulse oximetry (measured with the Philips IntelliVue MP30 patient monitor, a reliable measurement is defined by pulsatile flow with a perfusion indicator value above 0.3) and an indication, determined by the treating physician, to determine the acid-base, 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 available 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 determining the alveolar to arterial oxygen gradient (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 invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 21-10-2019

Enrollment: 155

Type: Actual

Ethics review

Approved WMO

Date: 16-07-2019

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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

CCMO

ID

NL70394.096.19