The effect of syringe volume on blood gas analysis

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Procedural related injuries and complications NEC
Study type	Observational non invasive

Summary

ID

NL-OMON55447

Source
ToetsingOnline

Brief title
Blood gas syringe study

Condition

- Procedural related injuries and complications NEC

Synonym
anemia, blood disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Blood gas/ syringe/ anemia/ neonatology

Outcome measures

Primary outcome

For all parameters measured on the blood gas analyser (pH, pCO2, pO2, sodium, potassium, chloride, calcium, glucose, lactate, hemoglobin, O2-hemoglobin, CO-hemoglobin, methemoglobin and H-hemoglobin) the results for the 1 ml blood gas syringes will not statistically vary from the results for the 3 ml blood gas syringes.

Secondary outcome

n.a.

Study description

Background summary

Iatrogenic anaemia is an important problem for patients at the intensive care unit and in neonatal care. To moderate negative impact of anaemia on the recovery in this group of patients, red blood cell transfusions or erythropoiesis stimulating agents are often used. As both treatments come with extra risks for the patients, it is important to work on less invasive methods preventing iatrogenic anaemia. One of the ways which proved to be successful is to minimize the blood lost upon blood sampling.

Study objective

The ultimate goal of our study is to reduce the amount of blood withdrawn for blood gas analysis, especially in the intensive care unit and in neonatal care by replacing regularly used 3 ml blood gas syringes with 1 ml blood gas syringes. The main objective is to test whether a 1 ml blood gas syringe can be used in a clinical setting compared to a regularly used 3 ml blood gas syringe. Secondary objective is to establish the minimal blood volume to what 1 ml blood gas syringe has to be filled and whether the blood is mixed well in the 1 ml

blood gas syringe.

Study design

From patients of the Adult Intensive Care Unit who have an arterial catheter, 1500**l of arterial blood will be collected in a 3 ml blood gas syringe for the regular blood gas analysis, and an additional 3600**l for the blood gas syringe study. For the blood gas syringe study 1800 *l (200 + 300 + 500 + 800) of blood will be collected in 4 independent 3 ml blood gas syringes and another 1800 *l (200 + 300 + 500 + 800) in 4 independent 1 ml blood gas syringes. Blood gas analysis will be performed on one designated Rapidlab 1265 blood gas analyser (Siemens, USA) according to manufacturer protocol. Results from 3 ml blood gas syringes and 1 ml blood gas syringes will be compared to evaluate whether 1 ml blood gas syringes perform equally good as regularly used 3 ml blood gas syringes. Results obtained with different fill volumes will be compared in order to check if the fill volume influences the results and to establish the minimal fill volume that gives reliable results. If results from 1 ml blood gas syringes are 1. agreeing with results from the regularly used 3 ml blood gas syringes, 2. minimal fill volume for the 1 ml blood gas syringes is lower than the volume currently withdrawn for the 3ml blood gas syringes (500 *l) and 3. the blood can be mixed well in the 1 ml blood gas syringes, the verification by means of patient comparison will be performed in 20 children and 20 neonates from the Paediatric Intensive Care Department and Department of Neonatology respectively. This verification in minors is necessary to eliminate possible variations related to differences in hematologic and rheologic properties of the blood between adults and children/neonates. For that from children/neonates one additional 1 ml blood gas syringe will be collected. The blood gas syringe will be filled with the minimum fill volume that has been established by testing different fill volumes in adults (see above). Results of the 1 ml blood syringe will be compared to the results of 3 ml blood gaseous syringe of regular blood gas analysis. Collected blood will not exceed 3% of the total circulating blood volume and no blood will be collected in the first week of life.

Study burden and risks

Patients will have an additional blood drawn from the arterial catheter (in children and neonates no more than 3 % of the total circulating blood volume) performed during the routine sampling in patient care.
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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

All patients, admitted to the relevant department, who have an arterial catheter and for who blood gas analysis is a part of standard patient care.

Exclusion criteria

All terminally ill patients. Patients for who blood gas analysis is not a part of standard patient care. Patients with reduced body temperature due to therapeutic hypothermia treatment. Neonates younger than 26 weeks. Neonates with a weight < 500g. Neonates with circulation of hemostasis problems

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-05-2018
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL62919.018.17