Arterial, venous and capillary blood gas measurement in newborn at the NICU.

Published: 21-12-2012
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The objective of this study is to investigate ABG, CBG and VBG (or parts of the blood gas analysis) in infants.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Acid-base disorders
Study type	Observational invasive

Summary

ID

NL-OMON40065

Source
ToetsingOnline

Brief title
Blood gas measurement in infants

Condition

- Acid-base disorders
- Neonatal respiratory disorders

Synonym
physiology

Research involving
Human

Sponsors and support

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

Intervention

Keyword: arterial blood gas, capillary blood gas, infants, venous blood gas

Outcome measures

Primary outcome

The aim of this study is to investigate whether arterial, capillary and venous

blood gasses (or parts of the blood gas analysis) are interchangeable.

Secondary outcome

The secondary aim is to investigate whether certain clinical circumstances

(e.g. respiratory, circulatory and infectious state) can influence the outcome

of these measurements.

Study description

Background summary

In NICU arterial blood gas sampling is the golden standerd to monitor ventilated patients.
Arterial access is not always technical possible and should always be well weighed against complications as trombosis, infection and ischemia.
In absence of arterial access, capillary blood gasses are used in standard of care. Because venous blood gasses are said to be unreliable, they are not used.
Even if due to other reason venous blood have to be drawn, a capillary blood gas will be taken seperately.
In literature there is lack of evidence whether the different blood gasses are, even partly, reliable enough to be used for clinical purposis.

Study objective

The objective of this study is to investigate ABG, CBG and VBG (or parts of the blood gas analysis) in infants.

Study design

This is a prospective observational single center study. In infants admitted to the NICU who need blood gas monitoring, arterial, venous and capillary blood

gas will be performed simultaneously at the same time-point.

Study burden and risks

To minimize the burden for the patient we will do the following:
When venous access is needed for either intravenous medication or for blood examination we will collect extra blood for venous blood gas at the same time.
We do not perform an extra puncture.
We will limit the number of simultaneously drawn blood gas samples to a maximum of 5 paired samples (e.g. venous versus arterial and/or capillary) and a maximum of 3 extra capillary punctures to minimize the burden per patient.

All punctures will be comforted with oral sucrosis following local protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All neonates who are in need of blood gas analysis for clinical purposis

Exclusion criteria

cor vitium

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):	07-02-2013
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-04-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	08-10-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL40693.058.12

Study results

Date completed:	23-07-2015
Actual enrolment:	93