Validation in healthy volunteers of a patented lactate probe designed for continuous intrapartum fetal monitoring of lactate levels

Published: 15-03-2017
Last updated: 11-04-2024

Primary Objective: to determine if lactate can be continuously and reliably measured by microdialysis in subcutaneous tissue in healthy volunteers

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43170

Source
ToetsingOnline

Brief title
Lactate probe in healthy volunteers

Condition

- Other condition

Synonym
acidification during exercise, exercise-induced lactate metabolism

Health condition

metabolisme bij hypoxie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Health-i-Care subsidie

Intervention

Keyword: Continuous, Healthy volunteers, Lactate, Sensor

Outcome measures

Primary outcome

Correlation between lactate levels measured in capillary blood and dialysate

from subcutaneous tissue with microdialysis.

Secondary outcome

Visual inspection of the agreement, R-squared values and Bland-Altman plots.

Ventilation, VO2, VCO2 parameters will be determined.

Study description

Background summary

In the developed world, it can be estimated that 80% of labors are continuously monitored with electronic fetal heart rate monitoring (EFM). A normal fetal heart rate pattern is seen when the fetus is well oxygenated. Abnormal tracings, which are seen in about 50% of labors, may be due to fetal hypoxia but in the majority of cases this is not the case. Since the introduction of EFM in the 1970*s there has been an escalation of operative deliveries - in USA now every third pregnancy ends in a caesarean delivery. Increased C-section rates are not associated with a lower incidence of encephalopathy from birth hypoxia, and lead to a 100% increase in healthcare costs for obstetrics.

A more direct method to monitor fetal oxygen supply is by measurement of fetal lactate levels. When hypoxia occurs, the energy metabolism of the fetus switches to anaerobic mode which produces lactate as a by-product. We developed a microdialysis probe integrated into the fetal scalp electrode used with EFM, allowing continuous measurement of lactate, giving instant information about the oxygenation status of the fetus. We have validated the probe in

anesthetized rats.

Study objective

Primary Objective: to determine if lactate can be continuously and reliably measured by microdialysis in subcutaneous tissue in healthy volunteers

Study design

Lactate measurements will be performed in a group of healthy volunteers during physical exercise on a bicycle ergometer. Continuous results from the lactate probe will be compared to lactate levels in capillary blood samples taken from the ear at fixed intervals during exercise.

Study burden and risks

Burden and risks consists of ear prick blood sampling, performing a strenuous exercise and insertion of the microdialysis probe.

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

Healthy, in good physical shape, over 18 years of age, informed consent has been signed and KNWU license

Exclusion criteria

Any major or chronic illnesses

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Microdialysis probe for continuous intracutaneous lactate measurement
Registration:	No

Ethics review

Approved WMO Date:	15-03-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-03-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL59630.042.16