Measurement of the sublingual microcirculation in critically ill children at the bedside: a pilot study

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To determine measurement reproducibility and analytical congruency in sequential measurements of the sublingual microcirculatory profiles at the bedside.

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

Summary

ID

NL-OMON55784

Source
ToetsingOnline

Brief title
sequential measurement microcirculation

Condition

- Other condition

Synonym
microcirculation

Health condition

microcirculatie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: beademing, critcally ill children, IDF imaging, microcirculation

Outcome measures

Primary outcome

The primary study parameter is to determine the within-patient reproducibility of the sequential measurement of the microcirculatory region of interest in critically ill children.

Secondary outcome

The second aim is to design a more practical way to analyze and interpret the microcirculatory bedside derived datasets. Sublingual microcirculatory measurements will be evaluated with a CytoCam, an optical spectroscopic sensor-based digital video imaging instrument (Braedius Medical BV, The Netherlands). Sublingual microcirculation profile consists of blood vessel diameter (BVd), proportion of perfused vessels (PVV), perfused vessel density (PVD), microcirculatory flow index (MFI) and total vascular density (TVD).

Study description

Background summary

Measurement of the sublingual microcirculation is an important additional parameter in critically ill patients. To view the microcirculation incident dark-field imaging is used and video-clips are recorded to evaluate blood flow. However, to date there still exist discrepancies in time consuming analyses of microcirculatory measurements obtained from two different time points and this

makes extrapolation of data for bedside diagnostics challenging.

Study objective

To determine measurement reproducibility and analytical congruency in sequential measurements of the sublingual microcirculatory profiles at the bedside.

Study design

Single center, prospective, observational pilot study.

Study burden and risks

This study uses a non-invasive technique to determine the sublingual microcircualtion. The procedure will be performed in children that are sedated because of mechanically ventilation. Because of these two aspects there is no burden and risk for the patient. It is an observational studie and therefore the patient has no benefit participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

-mechanically ventilation for at least 24 hours
-sedation
-0-18 years

Exclusion criteria

-no written informed consent from both parents

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	04-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2019
Application type:	Amendment
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	NL69233.018.19