Effects of propofol on microcirculation in children

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To obtain intermittent buccal and continuous sublingual microcirculatory profiles by sidestream dark-field imaging before and after induction of propofol by non-invasive diagnostics in infants and children.

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

Summary

ID

NL-OMON43768

Source
ToetsingOnline

Brief title
Propofol and microcirculation

Condition

- Other condition

Synonym
microcirculation

Health condition

circulatie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: geen extra kosten aan het onderzoek verbonden

Intervention

Keyword: microcirculation, propofol, SDF imaging

Outcome measures

Primary outcome

The main study parameter is to determine the effect of propofol on buccal and sublingual microcirculation in children.

Both buccal and sublingual microcirculations will be evaluated with a CytoCam an optical spectroscopic sensor-based digital video imaging instrument (Braedius Medical BV, The Netherlands). The buccal capillary density will be quantified by mean buccal capillary density and functional capillary density (FCD). 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).

Macrocirculation will be monitored by blood pressure and heart rate and hemoglobin oxygen saturation by pulse oximetry.

Secondary outcome

not applicable

Study description

Background summary

Propofol is the first choice sedative agent used for procedural sedation. Propofol has significant hemodynamic effects. It decreases vascular tone and reduces venous return, which is reflected by significant hypotension. Arterial hypotension associated with the induction and infusion of propofol is mainly a result of a decrease in afterload without compensatory increases in heart rate or cardiac output (Claeys et al. Br J Anaesth 1988;60:3-9). However, evaluation of macrocirculation by measuring blood pressure does not reflect microcirculation.
Only two studies have been performed in adult humans using non-invasive radiological imaging techniques to study the effect of propofol on microcirculation. No studies have been performed in infants and children.

Study objective

To obtain intermittent buccal and continuous sublingual microcirculatory profiles by sidestream dark-field imaging before and after induction of propofol by non-invasive diagnostics in infants and children.

Study design

Single center, prospective, observational study.

Study burden and risks

Subjects will have no direct benefits of participating in this study. Due to the observational character of this study, the risks are minimal. We aim to assess the above presented objectives using a video microscope system (CytoCam), which is a non-invasive techniques. No adverse events have been reported using this instrument. The only possible burden could be that some minor manipulation of the camera in the mouth of the child may be required to obtain qualitatively good images. No blood samples will be obtained.

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

-procedural sedation with propofol
-children 8-18 years

Exclusion criteria

no written informed consent

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):	18-02-2015
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	18-02-2015
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	NL51821.018.14