Intra-stomal and sublingual spectroscopy in septic and non-septic Intensive Care patients; effect of Nitroglycerine, Phenylephrine and Norepinephrine.

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What is the base-line StO2 reference value in intestinal stoma's. ? Is NIRS a reliable detector of intestinal ischamia ? What is the influence of filling-status on StO2 in the stoma and sublingually ? What is the influence of NTG on StO2 in the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON33896

Source
ToetsingOnline

Brief title
NIRS in intestinal stoma's and sublingual of intensive care patients.

Condition

- Vascular disorders NEC

Synonym
Intestinal ischaemia or lack-of-oxygen

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: Wetenschaps cie. of eigen budget van de Intensive Care.

Intervention

Keyword: intensive care, nitroglycerine, norepinephrine, phenylephrine, sepsis, side stream dark-field, spectroscopy, stoma's, sublingual

Outcome measures

Primary outcome

Base-line NIRS data in stoma and sublingually.

NIRS data in stoma and sublingually after "Passive leg raising"; "fluid

challenge"; NTG, PE and NA.

Difference in septic and non-septic patients.

Relation NIRS data and systemic haemodynamic parameters.

Base line NIRS data in stoma and sublingually on day 3.

Secondary outcome

Not relevant.

Study description

Background summary

Global and local intestinal ischaemia is a serious threat to Intensive Care Unit (ICU) patients. Global intestinal ischaemia is a potential precursor of sepsis and multiple organ failure (Crit Care. 2005;9 Suppl 4:S13-9. Epub 2005 Aug 25). Diagnosing intestinal ischaemia in the ICU setting is a problem. Scopy is often difficult; bowel preparation beiing absent or inadequate. Also, only a limited part of intestine can be observed with coloscopy. Serum lactate is only an indirect diagnostic parameter. Recently, orthogonal polarisation spectroscopy (OPS) has been used as a monitor of microcirculation in stoma's of ICU patients (Crit Care Med. 2007 Apr;35(4):1055-60). Other studies investigated OPS/SDF sublingual in septic Intensive Care patients, and the effect of various vasotonic agents. However, OPS does not give information about the tissue oxygenation, as Near Infrared Spectroscopy (NIRS) does. NIRS

has been validated for Hypovolaemic shock states on the thenar eminence of trauma patients. We hypothesise, that NIRS could be a potential instrument to detect intestinal ischaemia via stoma, and monitor the effects of often used vasotonic drugs on the ICU, such as nitrogglycerine (NTG), Phenylephrine (PE) and Norepinephrine (NA). Differences between septic and non-septic patients need to be studied, as changes in microcirculation in septic patients could potentially influence drug effect. Furthermore, correlations of sublingual NIRS data will be compared with NIRS data in stoma's, and OPS/SDF data in the literature.

Study objective

What is the base-line StO2 reference value in intestinal stoma's. ?
Is NIRS a reliable detector of intestinal ischamia ?
What is the influence of filling-status on StO2 in the stoma and sublingually ?
What is the influence of NTG on StO2 in the stoma and sublingually ?
What is the influence of PE on StO2 in the stoma and sublingually ?
What is the influence of NA on StO2 in the stoma and sublingually ?
Is there a difference in StO2 baseline and intervention values, betweeen septic and non-septic patients ?
What is the correlation between StO2 in stoma and sublingually, on day 1 resp day 3 ?
What is the correlation between NIRS data in the stoma and sublingual, and SDF/OPS data in the literature ?
What is the correlation between NIRS data and systemic haemodynamic parameters ?

Study design

Twenty four ICU patients with an enterostomie will be included in the study. Fifty percent of patients will be septic (ESICM criteria) and 50 % non-septic. Both mechanically ventilated patients and patients with spontaneous ventilation will be included. Patients with spontaneous ventilation can be on or off the ventilator.
Non-invasive cardiac output/index measurement via arterial Pulse Contour Analysis technique (Vigileo ® by Edwards). Patients will have routine arterial cannulation.
Serum lactate base-line via arterial catheter (this is already routine on our ICU).
If the patient has a Central Venous Catheter (CVC), a SvO2 or mixed venous saturation wil be measured pre and during interventions. CVC will not be introduced specifically for this study. Baseline haemodynamic parameters and SvO2. Baseline NIRS measurement on the thenar eminence.
Measurements of baseline physiologic fluctuations of NIRS data in stoma for a period of 30 minutes. Base line values of NIRS sublingually.
Because NIRS data are not validated for this application, these data may not

influence clinical decision making. Therefore, NIRS data will be unavailable to, and shielded from, attending clinicians.
Intravascular fluid status will be assessed with a "passive leg raising test" (PLRT).
Patients are randomised in four equal groups: 1) septic patients receiving Norepinephrine (NE) respectively Nitroglycerine (NTG); 2) septic patients receiving Phenylephrine (PE) resp. NTG ; 3) non-septic patients receiving NE resp. NTG; 4) non-septic patients receiving PE resp. NTG. If NE is already given, the dose is increased. Effect of fluid optimalisation on NIRS data in stoma and sublingually.
With a titrating-to-effect-technique, starting with a low dose continuous infusion, a change of 10 * 20 % in mean arterial pressure (MAP) is generated (decrease with NTG; increase with PE and NE). After 10 minutes of "steady state", StO2 in the stoma and sublingually are measured. Also, SvO2 is measured if patient has a CVC. After 15 minutes of "wash out", the second vasotonic agent is started. The MAP has to be > 60 mmHg and < 100 mmHg at all times. Atropine 0.5 mg and Ephedrine 5 mg iv are "stand by" as rescue medication. If *rescue medication* is administered, a wash out period of 15 minutes will be applied. Patient will have a minimum of 2 adequate infusions with a minimum Gauge of 18. NTG, PE and NE can be infused via peripheral infusions as long as infusion time is short (< 1 h).
Nitroglycerine: start 0,5 ug/kg/min.
Phenylephrine challenge: start 0,1. ug/kg/min.
Norepinephrine: start 0,1 ug/kg/min or increase in septic patients.
After second vasotonic agent: stop study.
On day 3: base line measurements of NIRS data in stoma and sublingually.

Intervention

Introduction NIRS and SDF probe/sensor in stoma.
"Passive Leg raising".
Optimalisation filling status with colloids with "Fluid Challenge".
Application of NTG, PE and NA.

Study burden and risks

See also E9A.

Introduction of NIRS probe in stoma and sublingually. NTG, PE and NA can influence Blood Pressure (BP), depening on Left Ventricular End Diastolic Pressures (LVEDP). NTG, PE and NA infusions are routine on the ICU and the Operation Ward. Haemodynamic monitoring will be done with invasive and continious arterial blood pressure monitoring. LVEDP will be optimalised. NTG, PE and NA will be titrated to effect and have very short effect life. Stopping the infusion will halt the effect on BP quickly.

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

Intensive care patients with an intestinal stoma. Septic versus non-septic patients.
Both ventilated and spontaneously breathing patients are included.

Exclusion criteria

Non-compliance of patient or relative. Dehiscence or serious oedema of the stoma. Serious haemorrhagic diathesis; platelet count < 60; INR > 3.0. Haemodynamic instability; mean arterial pressure (MAP) < 60 mmHg or < 40 % baseline. Hypertension; MAP > 100 mmHg or > 20 % baseline. Patients with anuria. Fractures or luxation of the legs/hips. Symptomatic myocardial ischaemia. Nitroglycerine infusion for therapeutic indications (myocardial ischaemia).

Serious laesions or infections of the mouth or tongue.
Ileostoma*s are relatively contraindicated for NIRS cannulation. Patiens with marked clinical signs of intraabdominal hypertension

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-08-2009
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	Introducing NIRS probe in intestinal stoma and sublingual
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-04-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	17-06-2009
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL20530.098.07