

The influence of artificial CO2 pneumoperitoneum and pneumothorax on tissue oxygenation and microcirculation in neonates: A pilot-study with Near InfraRed Spectroscopy and Sidestream Dark Field Image Analysis

Published: 30-03-2011

Last updated: 04-05-2024

To evaluate the tissue-oxygenation and microcirculation before, during and after application of artificial pneumoperitoneum/-thorax using Near Infrared Spectroscopy (NIRS) and Sidestream Dark Field Imaging (SDF) and validate the usefulness of these...

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

Summary

ID

NL-OMON36496

Source

ToetsingOnline

Brief title

LAPMICROCIRC

Condition

- Other condition
- Congenital and hereditary disorders NEC
- Breast therapeutic procedures

Synonym

microcirculation, tissue oxygenation

Health condition

Operaties wegens met name congenitale hernia diafragmatica en slokdarmatresie

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: intraoperative monitoring, laparoscopy, neonates, spectroscopy

Outcome measures**Primary outcome**

Tissue-oxygenation, measured by conventional methods and NIRS/SDF

Secondary outcome

Hormonal stress-respons to minimal access surgery (CO₂ insufflation)

Study description**Background summary**

Minimal access surgery has many advantages. Less trauma to body-tissues means smaller scars and faster post-operative recovery. In neonates, CO₂ pneumoperitoneum and pneumothorax have a major effect on hemodynamics. Acidosis occurs, and measuring tissue-oxygenation is done by bloodgas analysis. The intermittent sampling causes lacunae in the information about the oxygenation of brain and other organs.

Whether less trauma to tissues leads to a decreased hormonal stress-respons is unknown. Insufflation of CO₂ might also be a stressor, but it's effect on stress-hormone levels is unknown.

Study objective

To evaluate the tissue-oxygenation and microcirculation before, during and after application of artificial pneumoperitoneum/-thorax using Near Infrared Spectroscopy (NIRS) and Sidestream Dark Field Imaging (SDF) and validate the usefulness of these techniques in monitoring neonates during Minimal Access Surgery. This will result in follow-up studies where these measurements will be used to make therapeutical interventions.

To compare the hormonal stress response during and after endoscopic surgery with historic data we have from neonates undergoing the corresponding open surgical procedures

Study design

Single-centre, non-randomized, observational study

Study burden and risks

All measurements will be done under anesthesia. Measurements are non-invasive, no radiation is involved. A small quantity of blood will be collected for determination of stress-hormone levels.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

All neonates 0-28 days of age

Endoscopic procedure, laparoscopy or thoracoscopy

Estimated duration of surgery more than 1 hour

Informed consent

Exclusion criteria

Inability to obtain informed consent from parents

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 30-04-2011

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 30-03-2011
Application type: First submission
Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL34637.078.10