Validation of blood bio-parameter and hemodynamic measurements by the noninvasive TensorTip MTX-Cnoga device

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28436

Source
Nationaal Trial Register

Brief title
Cnoga- 20 MAL

Health condition

hemodynamic insatbility during surgery

Sponsors and support

Primary sponsor: non
Source(s) of monetary or material Support: Department of Anaesthesiology, Pain and Palliative Medicine, Radboud University Medical Centre

Intervention

Outcome measures

Primary outcome

comparison of hemodynamics and bio-parameters with Bland-Altman analysis.

Secondary outcome

other parameters by the device like saturation, heartrate, stroke volume

Study description

Background summary

The aim of the study is to compare three parameters of the MTX Gnoca (hemodynamics, hemocytometry and blood gas values) with the same values that are part of the standard care. Only if there are measurements performed on the patient as part of standard care, the tested device will be used. The Cnoga is a small device(comparable to a pulse oximeter) which is very easy to put on. Cnoga's technology is based on four Light Emitting Diodes (LED) in a finger compartment. These LEDs send visible to infrared light rays on the fingertip, where detection takes place. While the light wave passes through the tissue and blood capillaries, some of the light is absorbed which changes the light signal. The remaining light wave is then projected on a sensor. The image sensor detects realtime changes in tissue color and the signal is transmitted to a processor and with an algorithm bioparameters are calculated.

Study objective

Comparison of the MTX Gnoca with golden standard for bloodpressure, cardiac output, hemoglobin and arterial bloodgas analysis.

Study design

Collection of data within three months. data analysis in two months. writing of papers in 3 months.

Primary outcome:
Hemodynamics: three measurements at the start of the surgery, after placement of arterial catheter/PiCCO. Measurements of blood pressure (arterial catheter)/CO (PiCCO) and at the same time three measurements with the CNOGA device. measurements of the CNOGA are visible on screen and can be connected with a phone/tablet. the measurements of blood pressure with the arterial catheter are directly visible on the patient monitor. Cardiac output measurement is done according to the advise of the menufacturer

Hemocytometry/bloodgas analysis: at the start of surgery one bloodgas and/or hemoglobin measurement is done and send to the laboratory of the radboudumc. At te same time three measurements with the Cnoga are performed. the mean of these measurements are used for the comprison with the laboratory measurements.

Secondary outcome:
Other parmaters (saturation, heartrate, stroke volume) are measured in the same way as the

hemodynamics. These measurements are directly visible on the patient monitor.

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

18 years or older
the patient must posses an arterial catheter, central line or PiCCO as part of their standard care.

Exclusion criteria

impossibility to place the MTX Gnoca
COVID-19 infection or suspected of infection.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-12-2020
Application type:	First submission

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
NTR-new	NL9164
Other	CMO regio Arnhem - Nijmegen : CMO dossiernummer: 2020-6660

Study results