Nociception Level monitoring in the Intensive Care

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25056

Source
NTR

Brief title
NEMO study

Health condition

Intensive care patients
Mechanical ventilation
Pain in sedated patients

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

- NOL index values up to 8 hours

Secondary outcome

- Blood pressure and heart rate;
- Drug administration;
- Nociceptive events will be collected on the eCRF;
- Patient age, sex and underlying condition.

Study description

Background summary

Several monitors are available that objectively track nociception in sedated or anesthetized patients. One such monitor is used at LUMC, the Nociception level (NOL) monitor (Medasense Biometrics Ltd). In this exploratory, non-interventional trial we will monitor the nociception level index (an index ranging from 0 = absence of nociception to 100 = intense nociception) in sedated and ventilated ICU patients to get an indication of the behavior of the NOL monitor in this specific patient population. The results of this observational trial will be used to power future studies on NOL-guided opioid and sedative administration.

Study objective

This is a hypothesis-free trial but expect similar behavior of the NOL-index in sedated and ventilated ICU patients compared to surgical patients.

Study design

Patients in the ICU of the LUMC will be screened for inclusion. Eligible patients will be connected to the NOL device via two electrodes and a finger cuff placed on dig. V. Although no harm has been observed from use of the finger cuff in patients treated so far at the LUMC, we will move the cuff at 4-6h intervals to another finger to ensure no skin damage due to cuff pressure. This is a preventive measure and not based on existing evidence though. Patients will be connected between 08:00 - 09:00 in the morning and will be disconnected after 8 hours of measuring.

Contacts

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Eligibility criteria

Inclusion criteria

- Aged 18 years or older
- Mechanical ventilation for any reason
- Deemed suitable by the investigators

Exclusion criteria

- Aged 17 years or younger
- Not deemed suitable by the investigators

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:	Pending
Start date (anticipated):	28-12-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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	NL9159
Other	WEC Intensive Care/Anesthesiology LUMC : A020-001

Study results