Effect of a bundle of non-pharmacological interventions on the stress response to surgery

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To assess the effect of a bundle of non-pharmacological interventions implemented in the post-anesthesia care unit on the total serum cortisol levels after intermediate and major surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON53770

Source
ToetsingOnline

Brief title
SPACU-lab

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Therapeutic procedures and supportive care NEC

Synonym
perioperative stress, surgical stress

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: gratis essentiële oliën en patches van Aromazorg Zuster en Chi Natural Life (geen geld),vanuit eigen vakgroepbudget en een gift van Stichting Patientenzorg AvL

Intervention

Keyword: perioperative stress, stress reduction, surgical stress

Outcome measures

Primary outcome

Serum cortisol levels on the first postoperative day.

Secondary outcome

The secondary endpoints are IL-6, NLR, CRP and glucose on postoperative day 1.

Study description

Background summary

Surgical trauma and post-surgical pain induce a physiological stress response that can be detrimental to the patient. Non-pharmacological interventions aimed at stress reduction are known to reduce pain scores and opioid consumption. The effect of these interventions on the surgical stress response are unknown.

Study objective

To assess the effect of a bundle of non-pharmacological interventions implemented in the post-anesthesia care unit on the total serum cortisol levels after intermediate and major surgery.

Study design

This is a prospective before-after study

Study burden and risks

The burden consists of:
- two questionnaires that consist of 15 questions and take a maximum of 5 minutes to complete
- one to a maximum of three extra venapunctures (depending on the specific surgical protocol).

There is no risk associated with the stress-reducing interventions. Patients with bronchial hyperreactivity will not be included to prevent adverse reactions to aromatherapy.

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

- 18 years or older
- ASA I-III
- Ability to give oral and written informed consent
- Scheduled to undergo elective surgery with an expected minimum duration of 120 minutes
- Scheduled to undergo intermediate to major risk surgery

Exclusion criteria

- Day case surgery
- Use of neuraxial anaesthetic technique
- Chronic use of steroids
- Indication for peri-operative steroids (e.g. COPD, adrenal insufficiency)
- Bronchial hyperreactivity
- Unable to give written or oral informed consent
- Patient refusal
- Planned for post-operative ICU admission
- ASA >= 4
- Scheduled for minor risk surgery (Levels of Surgical Complexity 1 and 2)

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-05-2023
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	05-04-2023
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	13-12-2023
Application type:	Amendment
Review commission:	METC NedMec

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
ClinicalTrials.gov	NCT05638152
CCMO	NL83295.041.22