

Implementation of a bundle of non-pharmacological interventions aimed at stress reduction in the PACU: effects on pain and use of opioids

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23536

Source

Nationaal Trial Register

Brief title

the SPACU study

Health condition

Surgical population

Sponsors and support

Primary sponsor: Investigator initiated

Source(s) of monetary or material Support: Stichting patiëntenzorg AVL

Intervention

Outcome measures

Primary outcome

Our co-primary endpoints will be the proportion of patients with moderate or severe pain

during their PACU stay and the proportion of patients requiring any opioid during their PACU stay.

Secondary outcome

Cumulative opioid dose in the PACU, highest NRS in the PACU, PACU length of stay, patient satisfaction at discharge from the PACU, incidence of PONV in the PACU, incidence of opioid-related adverse events during hospital admission, persistent use of opioids at discharge.

Study description

Background summary

Surgical stress, pain and anxiety activate a stress response that can negatively influence post-operative outcomes. This stress response can be influenced by pharmacological and non-pharmacological interventions. Opioids are the cornerstone for the treatment of moderate to severe postoperative pain. However, opioids are associated with adverse respiratory events and opioid addiction. In the U.S, 10% of opioid-naïve patients with cancer undergoing curative-intent surgery develop new persistent opioid use. Non-pharmacological interventions that are aimed at reducing stress have been shown to be cheap, low-risk interventions that affect pain perception and patient outcomes positively.

For this study, a bundle of non-pharmacological interventions will be implemented in the post-anesthesia care unit. The bundle consists of:

- a) access to natural elements in the PACU
- b) positive distraction through music
- c) aromatherapy
- d) introduction of communication techniques that enhance placebo effects and reduce nocebo effects of communication

The effect of the bundle on pain, use of opioids, length-of-stay, opioid-related side-effects and adverse events, patient satisfaction and staff satisfaction will be compared to the 6 months prior to implementation of the bundle.

Study objective

The implementation of a bundle of pharmacological interventions aimed at stress reduction leads to lower pain scores and lower use of opioids in the PACU

Study design

Before arm: 6 months data gathering
Implementation of the bundle

After arm: 6 months data gathering

Intervention

1. Acces to nature (full lenght wall coverings and leighted ceiling pannels with nature images)
2. Positive distraction through music
3. Aromatherapy
4. Comfort Talk communication course for nurses

Contacts

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Eligibility criteria

Inclusion criteria

Patients from all surgical disciplines undergoing surgery with a minimum duration of 2 hours and a minimal hospital length of stay of 1 postoperative night will be eligible for inclusion.

Exclusion criteria

Use of neuraxial anesthesia or analgesia, a history of psychiatric illness, chronic pain conditions or chronic use of opioids.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2022
Enrollment:	1066
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

NTR-new

Other

ID

NL9835

METC AVL : METC 031

Study results