The influence of the ingestion of ice after surgery on pain and nausea and vomiting.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21388

Source
NTR

Brief title
IceCo study

Health condition

Postoperative pain and postoperative nausea and vomiting.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Primary outcomes include:

1) Postoperative pain in the first 24 hours after surgery

2) Analgesic consumption in the first 24 hours after surgery

3) Postoperative nausea and vomiting in the first 24 hours after surgery

Secondary outcome

Secondary outcomes include:

1) Sedation in the first 24 hours after surgery

2) Pain in the throat in the first 24 hours after surgery

Study description

Background summary

Postoperative pain and postoperative nausea and vomiting (PONV) are common after surgery and a large burden to patients. Not only the site of surgery may be painful but also anesthesiological interventions, like intubation and the insertion of an urinary catheter may result in discomfort after surgery. For example, oral intubation may lead to a sore throat and hoarseness and the placement of a urinary catheter may result in discomfort in the urinary tract. PONV is often caused by surgical interventions in the abdomen but also drugs necessary to induce anesthesia result in postoperative nausea and vomiting.

The management of postoperative pain and PONV is one of the tasks of the recovery personnel under supervision of the anesthesiologist. Management of postoperative acute pain is often by the administration of opioids (which by themselves are a main cause of PONV). PONV is treated by the administration of anti-emetic drugs. In addition to pharmacological interventions, non-pharmacological interventions may be very useful in the treatment of postoperative pain and PONV. However, currently, non-pharmacological interventions are not routinely used in the recovery room for the management of pain or nausea and vomiting, possibly because their effectiveness has never been investigated. Non-pharmacological interventions have been successfully used in the first week after surgery. For example, it has been shown that chewing gum in the first week after abdominal surgery reduces the development of postoperative ileus.1

In the current study we will investigate the effect of non-pharmacological treatment on postoperative acute pain and PONV in patients undergoing a laparoscopic cholecystectomy. Patients will receive an ice-lolly, chewing gum or no non-pharmacological treatment in the postoperative phase. We believe that this non-pharmacological treatment can reduce the

stress level of patients direct postoperative and can give distraction from the pain and nausea. This may result in a reduction of pain intensity levels and analgesic consumption and a lower incidence of PONV in patients using ice-lolly or chewing gum postoperatively.

Study objective

We hypothesize that:

1) Patients receiving an ice-lolly or chewing gum directly postoperative will have lower pain intensity scores in the 24 hours following surgery compared to no non-pharmacological treatment.

2) Patients receiving an ice-lolly or chewing gum directly postoperative will have a reduced analgesic consumption in the 24 hours following surgery compared to no non-pharmacological treatment.

3) Patients receiving an ice-lolly or chewing gum directly postoperative will have a lower incidence of PONV and need less anti-emetic drugs in the 24 hours following surgery compared to no non-pharmacological treatment.

Study design

All outcome parameters will be measured at predefined time points: 15 minutes prioir to surgery and at 0, 15, 30, 45 and 60 minutes and 3, 12 and 24 hours after the end of anesthesia.

Intervention

The study will have two interventions:

1) ingestion of an ice-lolly direct post-operative

2) 20 minutes chewing of chewing gum direct post-operative

11-dec-2016: Due to too severe postoperative sedation we cancelled the chewing gum intervention arm. In the first 3 patients who received chewing gum 2 patients fell asleep during chewing of the gum which was considered too dangerous by the investigators due to the risk of airway obstruction by the gum. Therefore, the study arm with chewing gum as intervention was removed from the study.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria include:

1) American Society of Anesthesiologists score 1, 2 or 3;

2) age 18 to 75 years;

3) planned for elective laparoscopic cholecystectomy

Exclusion criteria

Exclusion criteria include:

(1) Pain scores > 3 (on a 11-point numerical rating scale, NRS) reported for most of the day during the past month;

(2) Regular use of analgesics for any purpose, including SNRIs, gabapentinoids, COX inhibitors or NSAIDs during the previous month;

(3) The presence of any chronic pain disorder;

(4) The presence of swallowing problems;

(5) Inability to give informed consent;

(6) Inability to communicate with the investigators;

(7) Known allergy to any component of ice-popsicles or chewing gum

(8) Inability to chew postoperatively

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2015
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-07-2015
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	NL5187
NTR-old	NTR5335
Other	- : P15-019

Study results

Summary results

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