

The perioperative reduction of pain and anxiety through visualization in patients undergoing laparoscopic cholecystectomy.

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Reduction of perioperative anxiety and pain through visualization and relaxation exercises in patients undergoing surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31949

Source

ToetsingOnline

Brief title

PROPAV

Condition

- Other condition

Synonym

Perioperative anxiety and pain

Health condition

Angst en pijnbeleving

Research involving

Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis

Source(s) of monetary or material Support: SKWOSZ Stichting Klinisch Wetenschappelijk Onderzoek Slotervaart Ziekenhuis

Intervention

Keyword: Patient satisfaction, Postoperative pain, Preoperative anxiety, Stress reduction, Visualization

Outcome measures

Primary outcome

The use of analgetics (particularly opiates according to the PCA-system) during the first 24 hours postoperatively.

Secondary outcome

Anxiety score

Pain score

Patient satisfaction score

Study description

Background summary

Stress, anxiety and pain have a negative influence on the recuperation of postoperative patients. Research has demonstrated the positive effect of mind-body techniques on anxiety and postoperative pain.

Study objective

Reduction of perioperative anxiety and pain through visualization and relaxation exercises in patients undergoing surgery.

Study design

Randomized open multicentre study.

Intervention

Visualization and relaxation exercise (psychological intervention).

Study burden and risks

Each patient will receive a thirty minute instruction about on the study by one of the researchers. The patient is asked to practice the visualization and relaxation exercise starting 7 days prior to surgery for about 20 minutes each. Shortly before surgery the patient will complete the anxiety questionnaire (APAIS = Amsterdam Preoperative Anxiety and Information Scale). During a period of 24 hours pain is scored (NRS-score) four times a day and the patient satisfaction questionnaire (PSQ 18) will also be completed before discharge from the hospital. We estimate the psychological risk to be minimal. No invasive techniques will be used.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age above 18 years
Patients requiring a laparoscopic cholecystectomy.

Exclusion criteria

Insufficient knowledge of the dutch language
Psychiatric history
Refusal
Patient doesn't possess the required audio equipment.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO	
Date:	27-10-2008

Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
CCMO	NL22277.048.08