Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Clinical trial comparing the effects of patient communication before general anesthesia on post-operation pain and agitation of patients after endoscopic sinus surgery in the recovery room

Protocol summary

Summary

This study evaluates the effect of patient communication before general anesthesia on post-operation pain and agitation. After getting approved by ethics committee of Mashhad University of Medical Sciences, 64 patients who were scheduled for sinus endoscopic surgery were allocated according to the block randomization to case and control groups. It was double blind for the patients and the researchers. The patients did not know about their groups and both groups were in the separated rooms in ward. Intervention groups were not informed in presence of the controls. Also another blind researcher from group assignment evaluated pain and agitation in recovery room. The patients, who were all over 18 years old and they were all non-smokers with no drug addiction or long-term (>6 months) use of analgesic and/or NSAIDs entered the study consecutively. The Patients who faced complications during anesthesia were excluded from the study. This study performed at Ghaem hospital, a Mashhad University of Medical Sciences affiliated hospital, from January to December 2011. The case group were involved in a 15-20 minutes of informative and supportive communication once in the night before the surgery and once again for 5-10 minutes just before the surgery. The control group did not receive that communication. The same technique for general anesthesia was performed for both groups. After surgery, all of the patients were under the care of one nurse who was kept blind to the patients' group in the recovery. Pain severity was estimated using visual analog scale and non-verbal analog scale. Agitation was scaled using Riker's Sedation-Agitation Scale. main outcome measures (variables): pain, agitation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404278589N3**
Registration date: **2014-11-04, 1393/08/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-04, 1393/08/13

Registrant information

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Fatemeh Hajimohamadi
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2011-05-23, 1390/03/02

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effects of patient communication before general anesthesia on post-operation pain and agitation of patients after endoscopic sinus surgery in the recovery room

Public title
The effect of communicating with patient before anesthesia on pain and agitation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria : patients, who were all over 18 years old and they were all non-smokers with no drug addiction or long-term (>6 months) use of analgesic and/or NSAIDs, Patients were diagnosed and scheduled for limited sinus endoscopy surgery (opening maxillary, ethmoid and sphenoid sinus with or without partial resection of middle cornea without septoplasty including polyposis and sinusitis) entered the study consecutively. Exclusion criteria: Patients who faced complications during anesthesia (cardiac arrest, bradycardia (HR<40) and bronchospasm), needed a more advanced sinus endoscopic surgery, in whom cautery was used for hemostasis or surgery, duration of longer than 4 hours were excluded from the study.
Age
From **18 years** old to **61 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **61**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Vakilabad St., Mashhad
City
Mashhad
Postal code
Approval date
2011-07-09, 1390/04/18
Ethics committee reference number
891029

Health conditions studied

1

Description of health condition studied
acute pain and agitation
ICD-10 code
R52.9, R45
ICD-10 code description
Generalized pain NOS, Worries NOS

Primary outcomes

1

Description
pain
Timepoint
Entering the recovery, During the recovery entrance, Leaving the recovery
Method of measurement
Visual Analog Scale, Non-verbal Analog Scale

2

Description
Agitation
Timepoint
Entering the recovery, During the recovery entrance, Leaving the recovery
Method of measurement
Riker Sedation-Agitation Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention1: The patients of case group were involved in a 15-20 minutes of informative and supportive communication once in the night before the surgery and once again for 5-10 minutes just before the surgery. All of the informative and supportive plans were designed by psychologists and anesthesiologist. Supportive communication plan include; the researcher introduces his/her self and asks the patients about their name, job, education, experience of their previous surgery. The researcher encourages the patients to express their feeling and anxiety about their surgery. Also assures the patients about their complete coverage during surgery.

And says that there is not any facial incision in your face in this surgery. We have not had any mortality in this kind of surgery in this hospital. Informative communication plan; the Patients are informed about general anesthesia and its equipment such as mask, anesthesia machine, ambo bag, monitoring, common side-effects that may occur during anesthesia, post-op pain, nausea, vomiting and how to control them. Also they are informed about how improve their breathing with closed nasal way and when they can eat and drink after surgery. They are informed about intra nasal pack (two days after surgery is removed) and some others routine actions (washing their nose with normal saline).

Category

Prevention

2

Description

Intervention2: The patients of control group did not receive any informative and supportive communication and were only treated with routine OR procedures. If they had some questions, the stuffs answered to patient's questions.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital, Mashhad

Full name of responsible person

Fatemeh Navidi, Master of Sciences in Nursing

Street address

Ghaem hospital, Daneshgah st, Mashhad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Mashhad University of Medical Sciences

Full name of responsible person

Jalil Tavakoli Afshari

Street address

Mashhad University of Medical Sciences, Mashhad

City

Mashhad

Grant name

1324/511

Grant code / Reference number

891029

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Navidi

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty