

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intravenous acetaminophen and remifentanyl on the airway response to tracheal tube in endoscopic sinus surgery, during and the end of anesthesia: a clinical trial study

Protocol summary

Summary

We conducted a double blind Randomized Clinical Trial to compare the effect of intravenous acetaminophen as an alternative for remifentanyl, with remifentanyl on airway response to tracheal tubes during and at the end of anesthesia in Functional Endoscopic Sinus Surgery(FESS). The study population consisted of 70 patient 20-50 years old with ASA1 eligibility criteria who were candidates for functional endoscopic sinus surgery in Rasoul Akram hospital. Patients were excluded with sensitivity to acetaminophen, sensitivity to narcotic drugs and diseases such as asthma and hypertensive. They randomly allocated in two groups: acetaminophen (n=35) and remifentanyl (n=35). Remifentanyl 0.1µg/kg/min was administered for both groups during anesthesia. In group I, Since the beginning of the nose tampon until extubation, remifentanyl infusion was continued, and in group II in the last 20 minutes of surgery, remifentanyl infusion was discontinued and intravenous injection of acetaminophen was began. Patient and prescribing were not aware of the nature of the drug and only operating room technician was aware of the prescribing drug(the study was double blind). Cough was assessed with 5-point rating scale that recommended by Minogue and colleagues:1. No cough and no stiffness 2.Calm cough and extubation easily 3. Moderate cough 4. Severe cough or muscle stiffness 5. Vigorous agitation for extubation in awake.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010714199N4**
Registration date: **2014-03-13, 1392/12/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-13, 1392/12/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2012-07-05, 1391/04/15

Expected recruitment end date

2013-07-21, 1392/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous acetaminophen and remifentanyl on the airway response to tracheal tube in endoscopic sinus surgery, during and the end of anesthesia: a clinical trial study

Public title

Intravenous acetaminophen and remifentanyl on the airway response in endoscopic sinus surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patient's desire to participate in the study and informed consent, ASA1 eligibility criteria, 20-50 years old, Candidate for sinus surgery. Exclusion criteria: Hypertensive, Asthma, Sensitivity to acetaminophen, Sensitivity to narcotic drugs, Chronic obstructive pulmonary disease, A sign of the difficult airway in examination, Aspiration risk, Recent infection of the airways, Chronic cough and liver disorders.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences Central Campus, Shahid Hemmat Highway, Adjacent to Milad Tower, Tehran, Iran

City

Tehran

Postal code**Approval date**

2011-06-11, 1390/03/21

Ethics committee reference number

273 / 91 / 3

Health conditions studied**1****Description of health condition studied**

cough

ICD-10 code

R05

ICD-10 code description

cough

Primary outcomes**1****Description**

Cough

Timepoint

At the end of surgery

Method of measurement

Observation and Minogue grading

Secondary outcomes**1****Description**

Heart rate

Timepoint

Heart rate was recorded at T0 (When the nasal tampons were inserted by surgeon), at T1 (During normal spontaneous breathing) and at T2 (5 min after tracheal extubation).

Method of measurement

Taking the pulse

2**Description**

The mean arterial pressure

Timepoint

The mean arterial pressure was recorded at T0 (When the nasal tampons were inserted by surgeon), at T1 (During normal spontaneous breathing) and at T2 (5 min after tracheal extubation).

Method of measurement

Pressure gauge

Intervention groups**1****Description**

In the first group, Remifentanyl infusion 0/1 µg/kg /min has continued since the nasal tampons were inserted by surgeon until trachea extubation.

Category

Prevention

2

Description

In the second group, remifentanyl infusion was discontinued at the last 20 minutes of operation and acetaminophen perfusion (1 gr diluted in 100 cc of normal saline solution with 50 cc syringes in the same remifentanyl syringes) was started by pump.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital, Ear-Nose-Throat [ENT]
operating room, Department of ear-Nose-Throat [ENT]

Full name of responsible person

Dr.Valiollah Hassani

Street address

Department of ear-Nose-Throat [ENT], Rasoul Akram
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of
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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran 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

Rasoul Akram Hospital, Ear-Nose-Throat [ENT]
operating room, Department of ear-Nose-Throat [ENT]

Full name of responsible person

Dr.Valiollah hassani

Position

Anesthesiologist

Other areas of specialty/work

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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