

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of nitrous oxide in post operative epigastric pain in the patients underwent general anesthesia with laryngeal mask airway

Protocol summary

Summary

Opinion: we know that the nitrous oxide gas can distend closed gas spaces of the body including stomach. Our opinion in this study is showing that the nitrous oxide gas can increase post operative gastric pain with aggravating laryngeal mask airway induced gastric distension or not? Inclusion criteria: 18-65 years old patients who scheduled for minor eye, orthopedic or general surgeries. Exclusion criteria: history of gastrointestinal problems, emergency operations, full stomach patients and patients with uncontrolled medical illness. Method and sample size: this study will be done on 160 patients with 18-65 years old ages who divide to 2 groups: group A who receive nitrous oxide and group B who won't. The technique of anesthesia is similar in other aspects. The patients will be assessed in post operative period to see whether these two groups are meaningfully different in reporting gastric pain or not?

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010420542N1**
Registration date: **2015-02-18, 1393/11/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-18, 1393/11/29

Registrant information

Name

Kazem Samadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 7636

Email address

ksamadi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Committee of Shiraz University of Medical Sciences; International Branch

Expected recruitment start date

2015-01-06, 1393/10/16

Expected recruitment end date

2015-02-05, 1393/11/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nitrous oxide in post operative epigastric pain in the patients underwent general anesthesia with laryngeal mask airway

Public title

The effect of nitrous oxide in post operative abdominal pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The 18-65 years - old patients scheduled for elective and minor eye, orthopedic or general surgeries which generally not exceed 45 minutes. Exclusion criteria: full stomach patients; emergency setting; trauma; morbid obesity (bmi more than 35); poor ventilation after laryngeal mask airway insertion; laparotomy; contraindication for nitrous oxide consumption; toothless patients; abdominal surgery; any

uncontrolled medical disease; extra dose of atracurium due to insufficient relaxation or prolongation of procedure

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **164**

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 Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Karimkhane zand Blvrd.

City

Shiraz

Postal code

Approval date

2014-11-22, 1393/09/01

Ethics committee reference number

CT-2014-246

Health conditions studied

1

Description of health condition studied

Abdominal pain

ICD-10 code

R10.1

ICD-10 code description

epigastric pain

Primary outcomes

1

Description

epigastric pain

Timepoint

one hr after operation

Method of measurement

subjective pain score

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group we eliminate nitrous oxide gas from anesthesia drugs.

Category

Other

2

Description

In control group the patients receive nitrous oxide gas as a routine anesthesia practice.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Marvdasht Shahid Motahhari Hospital

Full name of responsible person

Kazem Samadi

Street address

Shahid Motahhari Hospital, Moallem Square

City

Marvdasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Committee of International Branch of Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Reza Panjeshahin

Street address

Central Office of International Branch of Shiraz University of Medical Sciences, No 24, Jehad sazandegi street, Azadi Square

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Committee of International Branch of Shiraz 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

Shiraz University of Medical Science

Full name of responsible person

Kazem Samadi

Position

Assistant Professor

Other areas of specialty/work

Street address

Department of anesthesiology, Shahid Faghihi Hospital, Karimkhane zand Blvd.

City

Shiraz

Postal code

Phone

+98 71 3233 7636

Fax

+98 71 3233 7636

Email

samadikazem@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Kazem Samadi

Position

Assistant Professor

Other areas of specialty/work

Street address

Department of Anesthesiology, Shahid Faghihi Hospital, Karimkhane zand Blvd

City

Shiraz

Postal code

Phone

+98 71 3233 7636

Fax

+98 71 3233 7636

Email

samadikazem@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Kazem Samadi

Position

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Other areas of specialty/work

Street address

Department of Anesthesiology, Shahid Faghihi Hospital, Karimkhane zand Blvd

City

Shiraz

Postal code

Phone

+98 71 3233 7636

Fax

+98 71 3233 7636

Email

samadikazem@yahoo.com

Web page address

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