

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of vitamin B12 infusion in prevention of nitrous oxide- induced homocysteine increase in patients undergoing general anesthesia for elective surgery

Protocol summary

Summary

The aim of this randomized double-blind clinical trial is to evaluate Effect of vitamin B12 infusion in prevention of nitrous oxide-induced homocysteine increase. A total of 60 patients, meeting eligibility criteria, will be randomly allocated into three equal groups. Group A: before surgery 1mg Vitamin B12 with 100ml normal saline will be infused, during surgery % 60 nitrous oxide will be prescribed and after end of surgery 100ml normal saline will be infused to patients. Group B: before surgery 100ml normal saline will be infused, during surgery % 60 nitrous oxide will be prescribed and after end of surgery 1mg Vitamin B12 with 100 ml normal saline will be infused to patients. Group C: before and after end of surgery 100ml normal saline will be infused and during surgery % 60 nitrous oxide will be prescribed to patients. For all patients, a standard protocol for anesthesia will be applied uniformly. After anesthesia, in recovery room, a nurse (A Blinded observer) presence or absence of nausea and vomiting in patients will be recorded. Blood samples for measurement of serum B12 and homocysteine will be conducted in two stages: A- After transferring the patient to the operating room and tend to participate in the study. B- 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209226803N3**

Registration date: **2012-09-30, 1391/07/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-30, 1391/07/09

Registrant information

Name

Abolfazl Firouzian

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1222 6655

Email address

a.firouzian@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin B12 infusion in prevention of nitrous oxide- induced homocysteine increase in patients undergoing general anesthesia for elective surgery

Public title

Effect of vitamin B12 infusion in prevention of nitrous oxide- induced homocysteine increase

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Informed written consent; ASA class I-

II; Age between 18 and 45 years; Elective surgeries that operation time is estimated at more than 2 hours. Exclusion criteria: Pregnancy; Emergency Surgery; Contraindications of nitrous oxide (such as Pneumothorax; Mechanical intestinal obstruction; Occlusion of the middle ear; Laparoscopic Surgery; Laser Surgery; Increased ICP); Intake of vitamin B12 and folate supplements before surgery; Contraindications of vitamin B12 and folate; Leber's disease; Patients with vitamin B12 or folate deficiency; megaloblastic anemia; Anesthesia in the past month; Smoking; Renal failure; hypothyroidism.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code

866-48175

Approval date

2011-12-21, 1390/09/30

Ethics committee reference number

90-5

Health conditions studied

1

Description of health condition studied

Nitrous oxide in general anesthesia

ICD-10 code

Y14

ICD-10 code description

Poisoning by and exposure to other and unspecified drugs, medicaments and biological substances, undetermined intent

Primary outcomes

1

Description

plasma homocysteine

Timepoint

before intervention, 24h after intervention

Method of measurement

blood sampling

Secondary outcomes

1

Description

nausa and vomiting

Timepoint

after intervention in the end of surgery

Method of measurement

Questionnaire

2

Description

plasma vit B12

Timepoint

before intervention, 24h after intervention

Method of measurement

blood sampling

Intervention groups

1

Description

before surgery 1mg Vitamin B12 with 100ml normal saline will be infused, during surgery % 60 nitrous oxide will be prescribed and after end of surgery 100ml normal saline will be infused to patients.

Category

Treatment - Drugs

2

Description

before surgery 100ml normal saline will be infused, during surgery % 60 nitrous oxide will be prescribed and after end of surgery 1mg Vitamin B12 with 100 ml normal saline will be infused to patients.

Category

Treatment - Drugs

3

Description

before and after end of surgery 100ml normal saline will be infused and during surgery % 60 nitrous oxide will be prescribed to patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Abolfazl Firouzian MD, Assistant Professor

Street address

Emam Khomeini Hospital, Amirmazandarani Ave.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Abolfazl Firouzian MD

Position

Anesthesiologist, Assistant Professor

Other areas of specialty/work

Street address

Emam Khomeini Hospita, Amir mazandarani Ave.

City

Sari

Postal code

4814839953

Phone

+98 15 1227 5038

Fax

+98 22 75038

Email

a.firouzian@mazums.ac.irab.firouzian@gmail.com

Web page address

www.mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Abolfazl Firouzian MD

Position

Anesthesiologist, Assistant professor

Other areas of specialty/work

Street address

Emam Khomeini Hospital, Amir mazandarani Ave.

City

Sari

Postal code

4814839953

Phone

+98 15 1227 5038

Fax

+98 22 75038

Email

a.firouzian@mazums.ac.irab.firouzian@gmail.com

Web page address

www.mazums.ac.ir

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