Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 surgery100ml 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 anesthetia, 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 surgery100ml 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
Anesthesilogist, 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