

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effect of intravenous nitroglycerine versus placebo the hemodynamic responses in patients undergo elective non-cardiac surgery: a double blind randomized clinical trial

Protocol summary

Study aim

To compare the effect of intravenous nitroglycerine versus placebo the hemodynamic responses in patients undergo elective non-cardiac surgery

Design

This is a double-blind randomized clinical trial, in which 78 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients undergo elective non-cardiac surgery who will refer to Besat Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years; Candidate for elective non-cardiac surgery; Weight less than 100 kg
Exclusion criteria: Using anti-hypertensive or anti-depressive drugs; Hyperthyroidism or hypothyroidism; Diabetes, renal failure, heart failure, or liver disorder; A history of myocardial infarction; Hypotension; Bradycardia

Intervention groups

Intervention group 1: Intravenous nitroglycerine 1 mic g/kg as single-dose before surgery
Intervention group 2: Intravenous nitroglycerine 2 mic g/kg as single-dose before surgery
Control group: Intravenous normal saline 5 ml as single-dose before surgery

Main outcome variables

Primary outcome: Measuring systolic blood pressure
Measuring diastolic blood pressure
Measuring heart rates

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N265**

Registration date: **2019-03-05, 1397/12/14**

Registration timing: **retrospective**

Last update: **2019-03-05, 1397/12/14**

Update count: **0**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intravenous nitroglycerine versus placebo the hemodynamic responses in patients undergo elective non-cardiac surgery: a double blind randomized clinical trial

Public title

Comparison of the effect of intravenous nitroglycerine versus placebo the hemodynamic responses in patients undergo elective non-cardiac surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 65 years; Candidate for elective non-cardiac surgery; Weight less than 100 kg

Exclusion criteria:

Using anti-hypertensive or anti-depressive drugs; Hyperthyroidism or hypothyroidism; Diabetes, renal failure, heart failure, or liver disorder; A history of myocardial infarction; Hypotension; Bradycardia

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1, on two sheets the name of the intervention 2 and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-08-20, 1397/05/29

Ethics committee reference number

IR.UMSHA.REC.1397.297

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

blood pressure

ICD-10 code

R03.0

ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

2**Description of health condition studied**

heart rate

ICD-10 code

O76

ICD-10 code description

Abnormality in fetal heart rate and rhythm complicating labor and delivery

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

Measuring systolic blood pressure

Timepoint

Before and 1, 3, 5 and 10 minutes after intubation

Method of measurement

Using sphygmomanometer

2**Description**

Measuring diastolic blood pressure

Timepoint

Before and 1, 3, 5 and 10 minutes after intubation

Method of measurement

Using sphygmomanometer

3**Description**

Measuring heart rates

Timepoint

Before and 1, 3, 5 and 10 minutes after intubation

Method of measurement

Using monitor machine

Secondary outcomes

empty

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

Intervention group 1: Intravenous nitroglycerine 1 mic g/kg as single-dose before surgery

Category

Treatment - Drugs

2**Description**

Intervention group 2: Intravenous nitroglycerine 2 mic g/kg as single-dose before surgery

Category

Treatment - Drugs

3**Description**

Control group: Intravenous normal saline 5 ml as single-dose before surgery

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital in Hamadan C

Full name of responsible person

Shabnaz Sharifi

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Shabnaz.sharifi@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Shabnaz Sharifi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Pooran Hajian

Position

Anesthesiologist

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available