

# 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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

**Street address**

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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

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

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**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

**Street address**

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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

Shabnaz.sharifi@gmail.com

**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

**Street address**

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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

pooranhajian567@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**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