# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Jun 2026

## Clinical effects of inhalational nitrous oxide 50% on childbirth anxiety in cesarean section under spinal anesthesia

## Protocol summary

**Summary**

Objective: Spinal anesthesia is used for cesarean section. When the parturient is anxious, may affect the cesarean process. We designed this study to determine anxiolytic effective of nitrous oxide (N2O) in women undergoing cesarean section under spinal anesthesia. Design of study: we present a randomized double blind clinical trial on 56 primygravid 18-45 years old parturients undergoing cesarean section under spinal anesthesiain, 1388. 28 of patients received 50% N2O in O2 via face mask and control group received pure O2 during surgery. In six special time before and during the surgery (preoperation, spinal injection, skin incision, uterine incision, birth time and recovery time) they were evaluated for anxiety and pain VAS. In addition the ephedrine dose used during the surgery, newborns apgar score and presence of amnesia, nausea and vomiting were recorded.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2012091510841N1**
Registration date: **2012-10-24, 1391/08/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2012-10-24, 1391/08/03

**Registrant information**

**Name**

Nahid Manuchehrian

**Name of organization / entity**

Hamedan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 81 1827 7012

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Hamadan University of Medical Sciences

**Expected recruitment start date**

2009-03-20, 1387/12/30

**Expected recruitment end date**

2010-03-20, 1388/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical effects of inhalational nitrous oxide 50% on childbirth anxiety in cesarean section under spinal anesthesia

**Public title**

Anxiolytic effect of N2O

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: primigravid patients; 18-45 years old; educated; scheduled for cesarean section under spinal anesthesia. Exclusion criteria: Pre-eclampsia & Eclampsia; Vavular Heart Disease; Respiratory Disease; Previous Nausea &Vomiting; Ear Disease or Surgery; Increased ICP; Anemia; Shock; Patient refusal.

**Age**

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

**Gender**

Female

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **56**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Hamadan University Of Medical Sciences
**Street address**
Hamadan University Of Medical Science, Medicine School, Mahdie Street
**City**
Hamadan
**Postal code**
**Approval date**
2008-11-22, 1387/09/02
**Ethics committee reference number**
16/35/9/116444

## Health conditions studied

### 1

**Description of health condition studied**
Childbirth Anxiety under spinal anesthesia
**ICD-10 code**
F53
**ICD-10 code description**
Mental and behavioural disorders associated with the puerperium, not elsewhere classified

## Primary outcomes

### 1

**Description**
Anxiety Level
**Timepoint**
Befor spinal anesthesia and During spinal anesthesia, Skin Incision, Uterine Incision, Birth Time, Recovery Time
**Method of measurement**
Anxiety VAS

## Secondary outcomes

### 1

**Description**
Heart rate
**Timepoint**
every 5 minutes up to 15 minutes and every 15 minutes up to the end of the operation.
**Method of measurement**
Puls oximetry

### 2

**Description**
Hallucination
**Timepoint**
During Surgery & Recovery Time
**Method of measurement**
Observation

### 3

**Description**
Nausea & Vomiting
**Timepoint**
During operation & Recovery Time
**Method of measurement**
Observation

### 4

**Description**
Systoilic & Diastolic Blood Pressure
**Timepoint**
every 5 minutes up to 15 minutes and every 15 minutes up to the end of the operation.
**Method of measurement**
Non Invasive Blood Pressure Monitoring

## Intervention groups

### 1

**Description**
Intervention group: inhalation N2O%50 with oxygen by anesthesia mask. Patients received O2 & N2O %50 from 3 minutes before spinal anesthesia until birth time.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: inhalation oxygen %100 by anesthesia mask. Patients received O2 %100 from 3 minutes before spinal anesthesia until birth.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Fatemy Hospital
**Full name of responsible person**
Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences
**Street address**
Fatemy Hospital, Mahdie Street
**City**
Hamadan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Hamadan University Of Medical Science, Vice chancellor for research
**Full name of responsible person**
Dr.Tavilany
**Street address**
School Medicine, Mahdie street
**City**
Hamadan
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Hamadan University Of Medical Science, Vice chancellor for research
**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**
Hamadan University Of Medical Sciences
**Full name of responsible person**
Nahid Manouchehrian
**Position**
Anesthesiologist, Assistant profesore of Anesthesiology
**Other areas of specialty/work**
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**Web page address**

## Person responsible for scientific inquiries

**Contact**
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Special Board of Anesthesia & Intensive Care
**Other areas of specialty/work**
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## Person responsible for updating data

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## 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*