

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 anesthesia, 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 Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

Email address

manouchehrian@umsha.ac.ir

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**

Systolic & 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**Street address**

Fatemy Hospital, Pasdaran street

City

Hamadan

Postal code**Phone**

+98 81 1827 7012

Fax

+98 81 1828 3939

Email

manouchehrian@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University Of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Special Board of Anesthesia & Intensive Care

Other areas of specialty/work**Street address**

Fatemy Hospital, Pasdaran Street

City

Hamadan

Postal code**Phone**

+98 81 1827 7012

Fax

+98 81 1828 3939

Email

nmanouchehrian@yahoo.com ;
manouchehrian@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University Of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Anesthesiologist

Other areas of specialty/work**Street address**

Fatemy Hospital, Pasdaran Street

City

Hamadan

Postal code**Phone**

+98 81 1827 7012

Fax

+98 81 1828 3939

Email

nmanouchehrian@yahoo.com ;
manouchehrian@umsha.ac.ir

Web page address

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