

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison effect of warm serum and Hot air Radiant on prevention of Headache - nausea and vomiting after cesarean surgery

Protocol summary

Summary

The purpose of this study is to compare two methods of using warm intravenous fluids and Hot air Radiant with routine patients Care on the severity of postoperative shivering, pain, anxiety and spinal anesthesia duration in spinal anesthesia patients. Patients were scheduled in class 1 and 2 Society of Anesthesiology America (ASA) under elective cesarean section will be selected. This study is a randomized controlled trial that will be implemented on 75 cesarean delivery surgery patients with spinal anesthesia. It will be double blind. Patients will be set in randomized three groups. Routine Care (Serum with Equal operation room temperature) will be used for Group 1, for group two will be used intravenous warm serum (37.5 ° C) and for group three will be used Hot air Radiant. The degree of shivering will be recorded in recovery room and tympanic temperature will be recorded from starting of surgery to end of recovery room. Pain, nausea and vomiting, post dural headache will be assessed in first 24h. Anxiety level will be evaluated pre and postoperation by Spielberger anxiety questionnaire. BP, HR and spinal anesthesia duration will be recorded and then compared groups in end.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020232361N1**

Registration date: **2017-05-27, 1396/03/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-27, 1396/03/06

Registrant information

Name

Hojjat Torkmandi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 263601135

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torkmandi.or@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

The project funding is provided through Semnan University of Medical Sciences.

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of warm serum and Hot air Radiant on prevention of Headache - nausea and vomiting after cesarean surgery

Public title

Comparison effect of warm serum and Hot air Radiant on post operative complication in cesarean surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria include: age between 20-60 years old; undergoing cesarean surgery under spinal anesthesia; and duration of surgery between .5 and 2 h.

Exclusion criteria include: Having a history of thyroid disease, use of anticholinergic drugs, patients with infection in surgical location, diabetic, emergency surgery; Having a history of headaches, Patients with very high weight BMI>35, Body Temperature>38 or <36, A history of motion sickness, Received blood products during surgery and emergency surgery.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, 5th Km
Damghan road, Semnan, Iran.

City

Semnan

Postal code

35198-99951

Approval date

2016-12-12, 1395/09/22

Ethics committee reference number

IR.SEMUMS.1395.157

Health conditions studied

1

Description of health condition studied

surgical complication of cesarean section

ICD-10 code

Y83.8

ICD-10 code description

Other surgical procedures

Primary outcomes

1

Description

bleeding

Timepoint

Intraoperative

Method of measurement

Weight change gases, and Long gases and blood volume
within the botel suction

2

Description

Core temperature

Timepoint

Every 15 minutes , before induction of anesthesia to the
end of Recovery

Method of measurement

Using a tympanic thermometer

3

Description

blood pressure

Timepoint

Before Surgery then every 15 minutes to the end of the
recovery

Method of measurement

Using cardiac pressure monitoring device

4

Description

shivering

Timepoint

After the intervention in recovery

Method of measurement

Three-point scale of shivering

5

Description

anxiety

Timepoint

Before Surgery- after surgery and then 6-12 and 24 h
after surgery

Method of measurement

spielberger anxiety questionnaire

Secondary outcomes

1

Description

nausea and vomiting

Timepoint

Since his arrival in recovery every six hours in first 24h

Method of measurement

Based on the VAS scale

2

Description

The duration of anesthesia

Timepoint

During the injection -end of operation and then every 15 min to complet motor and sensory recovery

Method of measurement

base on Bromage scale

3

Description

pain

Timepoint

every 6h and before analgesics druge Prescription

Method of measurement

base on VAS scale

4

Description

Anxiety

Timepoint

before operation- post operation- 6,12 and 24 h after operation

Method of measurement

base on Spielberger questionnaire

Intervention groups

1

Description

Control group: receiving Serum with Equal operation room temperature and without Hot air Radiant.

Category

Treatment - Drugs

2

Description

The first intervention group: This group of patients recived warm intravenous serum(37.5 degrees) For complet time of surgery and recovery.Heating serum is by Hot Line Manufacturing Co. Hotline® Blood and Fluid Warmer Smiths medical model level1.The device is placed over the head tube and Continuously heats.

Category

Prevention

3

Description

Patients in the intervention group II: This group of similar patients in the control group, except that after entering the recovery room warm air radiation (by heating warm-med making Turkey) to the end of his time in recovery are receiving.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Dr Banafshe moshak

Street address

Kamali Hospital, Shohada square, Karaj

City

karaj

2

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Forozeshfard Mohammad

Street address

Semnan - B basij - Semnan University of Medical Sciences

City

semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

prof. Ali Rashidipoor

Street address

Semnan University of Medical Sciences, End of Basij Avenue, Semnan, Iran.

City

semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

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Person responsible for general inquiries

Contact

Name of organization / entity
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Other areas of specialty/work
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Person responsible for updating data

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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