

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Investigation and comparison of the effect of two different marcaine temperatures on shivering during and after cesarean section

Protocol summary

neuraxial anesthesia defined by Crossley and Mahagan.

Study aim

Determining and comparing the effect of two different marcaine temperatures on shivering during and after cesarean section

Design

Patients are randomly divided into two groups of 32 using a table of random numbers: Marcaine receiving group stored at operating room temperature (24 ° C) at 2.5 cc Marcaine receiving group stored at refrigerator temperature (4 degrees) at the rate of 2.5 cc In order to perform random allocation between the two groups, random allocation software version 1 was used under Windows. First, a sequence of random numbers from 1 to 64 with letters A, B (intervention and control) was prepared by the software. The first eligible participant The number 1 and the last person get the number 64 and based on the list of the type of treatment, it is determined that the clinical trial with a control group with parallel randomized blind groups of phase 4 is performed on 64 patients.

Settings and conduct

The study in the obstetrics and gynecology ward of Shahid Sadoughi Hospital in Yazd will be performed on women candidates for cesarean section.

Participants/Inclusion and exclusion criteria

Entry items: Women candidates for cesarean section in the age range of 20 to 38 years with GA 36 to 40 weeks. Cases of non-entry: People with local anesthesia, hypersensitivity to amide local anesthesia, history of headache and severe preeclampsia.

Intervention groups

Participants in the study are randomly divided into two groups of 32: in the intervention group, participants will receive marcaine stored at refrigerator temperature (4 degrees) and in the control group, participants will receive marcaine stored at operating room temperature (24 degrees).

Main outcome variables

Shivering from 0 to 4 by a special shivering scale for

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210816052206N1**

Registration date: **2021-12-29, 1400/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-29, 1400/10/08**

Update count: **0**

Registration date

2021-12-29, 1400/10/08

Registrant information

Name

marjan chalabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 8364

Email address

marjan.chalabi1614@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and comparison of the effect of two different marcaine temperatures on shivering during and after cesarean section

Public title

Investigation and comparison of the effect of two different marcaine temperatures on shivering during and after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women candidates for cesarean section in the age range of 20 to 38 years with GA 36 to 40 weeks.

Exclusion criteria:

People with local anesthesia, hypersensitivity to amide local anesthesia, history of headache and severe preeclampsia.

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Random allocation software version 1.0 under Windows, we generate a random sequence by a simple random allocation method.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to perform random allocation between the two groups, random allocation software version 1 was used under Windows. First, a sequence of random numbers from 1 to 64 with letters A, B (intervention and control) was prepared by the software. The first eligible participant The number 1 and the last person take the number 64 and it is determined based on the list of the type of treatment of the person. In order for the random allocation to be blind, the random allocation list is given to another person who is not involved in the research.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.SSU.MEDICINE.REC.

Street address

Alam Square, Shohadaye gomnam Boulevard, Shahisadoughi University of medical Science, Yazd , Iran

City

YAZD

Province

Yazd

Postal code

8916885346

Approval date

2021-11-09, 1400/08/18

Ethics committee reference number

1400.300

Health conditions studied

1

Description of health condition studied

Shivering during and after cesarean section

ICD-10 code

R00-R99

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes

1

Description

Shivering

Timepoint

During cesarean section until the end of the patient's recovery time

Method of measurement

Specific shivering scale for neuraxial anesthesia as defined by Grassley and Mahagan 0: No chills, 1: No muscle activity is visible but there is flexibility or contraction of peripheral arteries or both 2: Muscle activity in only one muscle group 3: Moderate muscle activity in more than one muscle group but no overall vibration 4: Activity Intense muscles that involve the whole body

Secondary outcomes

1

Description

Central body temperature

Timepoint

Every 5 minutes from the beginning of cesarean section for the first 20 minutes, then every 10 minutes to 30 minutes, and finally every 15 minutes until the end of the recovery time

Method of measurement

OMRON brand tympanic thermometer

2

Description

Sensory block surface

Timepoint

Every 5 minutes from the start of cesarean section for the first 20 minutes and then every 10 minutes to 30 minutes

Method of measurement

PINPRICK test

3

Description

Hemodynamic variables

Timepoint

Every 5 minutes from the beginning of cesarean section for the first 20 minutes, then every 10 minutes to 30 minutes, and finally every 15 minutes until the end of the recovery time

Method of measurement

Blood pressure and heart rate monitor

4

Description

Nausea and vomiting

Timepoint

5 minutes after the start of cesarean section until the end of the recovery time

Method of measurement

Sick symptoms

5

Description

Need an analgesic supplement

Timepoint

5 minutes after the start of cesarean section until the end of the recovery time

Method of measurement

Request the patient to receive an analgesic supplement according to the symptoms

Intervention groups

1

Description

Women candidates for cesarean section in the age range of 20 to 38 years with GA36 up to 40 weeks under anesthesia with marcaine stored in the refrigerator

Category

Prevention

2

Description

Control group: Women candidates for cesarean section in the age range of 20 to 38 years with GA36 up to 40 weeks under anesthesia with marcaine stored at operating room temperature

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

اتاق عمل کوثر بیمارستان شهید صدوقی یزد

Full name of responsible person

مرجان چلبی

Street address

ایران یزد میدان کاج خیابان ایثار خیابان بهاران کوچه بهاران ۱۴
پلاک ۱۴

City

yazd

Province

Yazd

Postal code

8916885346

Phone

+98 35 3823 1328

Email

marjan.chalabi1614@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Marjan Chalabi

Street address

No. 14, Baharan 14 alley, Baharan St, Eisar St, Kaj Square, Yazd, Iran

City

yazd

Province

Yazd

Postal code

8916885346

Phone

+98 35 3823 1328

Email

Marjan.Chalabi1614@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

1

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**

Yazd University of Medical Sciences

Full name of responsible person

Marjan Chalabi

Position

دستیار بیهوشی

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

Street address

ایران یزد میدان کاج خیابان اینار خیابان بهاران کوچه بهاران ۱۴

پلاک ۱۴

City

Yazd

Province

Yazd

Postal code

8916885346

Phone

+98 35 3823 1328

Email

Marjan.Chalabi1614@gmail.com

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

Yazd University of Medical Sciences

Full name of responsible person

Marjan chalabi

Position

دستیار بیهوشی

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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City

yazd

Province

Yazd

Postal code

8916885346

Phone

+98 35 3823 1328

Email

marjan.chalabi1614@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Marjan Chalabi

Position

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Phone

+98 35 3823 1328

Email

Marjan.Chalabi1614@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

This study will not have any side effects for the participants in the project

When the data will become available and for how long

Upon completion of data collection

To whom data/document is available

همه گروه های پزشکی

Under which criteria data/document could be used

In order to achieve the optimal temperature to reduce chills and after cesarean section and prevent unwanted complications

From where data/document is obtainable

Samples collected from women candidates for cesarean

section, which will finally be handed over to the archives of Shahid Sadoughi Hospital in Yazd

What processes are involved for a request to access data/document

Request, approval and delivery from the archives of Shahid Sadoughi Hospital in Yazd

Comments