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

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 alloction 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 neuraxial anesthesia defined by Crossley and Mahagan.

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 allocationation 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 alloction 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,Shahis sadoughi 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 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

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
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Other areas of specialty/work
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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
دستیار بیهوشی
Latest degree
Medical doctor
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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