

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the effect of local cold, heat and intermittent heat-cold application on pain intensity after cesarean section

Protocol summary

Study aim

Comparing the effect of local cold, heat and intermittent heat-cold application on pain intensity after cesarean section

Design

A clinical trial with control group, parallel group, not blinded, with 80 patients. The randomization is performed according to randomized block design.

Settings and conduct

For performing the study, the research samples placed randomized in study groups. The randomization is performed according to randomized block design.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients after cesarean section; Communication ability Exclusion criteria: Occurring crisis condition; Alteration in patient status; First-born mothers

Intervention groups

The first group: application of local coldness The second group: application of local heat The third group: intermittent heat-cold application The fourth group: routine care

Main outcome variables

Pain intensity after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101108005134N13**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **prospective**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Ali Fakhr-Movahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4192

Email address

Alimovi49@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2022-03-12, 1400/12/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of local cold, heat and intermittent heat-cold application on pain intensity after cesarean section

Public title

Comparing effect of local cold, heat and intermittent heat-cold application on pain intensity after cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients after cesarean section Communication ability

Age between 18 to 35 years

Exclusion criteria:

Occurring crisis condition Alteration in patient status
First-born mothers

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Study samples are randomly assigned to study groups after selection. Study samples are allocated equally to the study groups by the permuted randomized block design with quadruple blocks. Random blocks are made using the following website:
<https://www.sealedenvelope.com/simple-randomiser/v1/lits>

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan university of medical sciences

Street address

Basij Blvd; The central headquarters of the mobilization of the Boulevard, Semnan University of medical sciences, Vice President for research and technology

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2020-04-21, 1399/02/02

Ethics committee reference number

IR.SEMUMS.REC.1399.036

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

The pain intensity after cesarean section

Timepoint

Before intervention and 20 minutes after intervention

Method of measurement

Visual analog scale of pain

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before intervention and 20 minutes after intervention

Method of measurement

Sphygmomanometer

2

Description

Pulse rate

Timepoint

Before intervention and 20 minutes after intervention

Method of measurement

Pulse oximetry device

3

Description

Respiration rate

Timepoint

Before intervention and 20 minutes after intervention

Method of measurement

Counting in one minutes

4

Description

Body temperature

Timepoint

Before intervention and 20 minutes after intervention

Method of measurement

Thermometer

Intervention groups

1

Description

Intervention group 1: application of local cold gel pack with zero to -5 centigrade degree for 20 minutes on cesarean section dressing

Category

Other

2

Description

Intervention group 2: application of local heat gel pack with 38 to 40 centigrade degree for 20 minutes on cesarean section dressing

Category

Other

3

Description

Intervention group 3: intermittent heat-cold application as first, 10 minutes of local heat and then 10 minutes of local cold are applied to cesarean section dressing by the gel pack

Category

Other

4

Description

Intervention group 4: usual care according to ward routine

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-al-Momenin hospital

Full name of responsible person

Dr. Seyed Mohammad Hosseini

Street address

Imam Hossein Sq., Shahid Mostafa Khomeini Blvd.

City

Semnan

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Postal code

3473135197

Phone

+98 23 3346 0055

Email

amirhos@semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Parviz Kokhaei

Street address

The Central Headquarters of Semnan University of Medical Sciences, Vice Chancellor for Research and Technology, Basij Blvd

City

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Province

Semnan

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3514799442

Phone

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Email

Info@semums.ac.ir

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

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

Semnan University of Medical Sciences

Full name of responsible person

Dr. Ali Fakhr-Movahedi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing School, Semnan University of Medical Sciences, Kilometer 5, Damghan Road

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3365 4192

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

1. The study protocol 2. The results of the study

When the data will become available and for how long

After termination of the study

To whom data/document is available

1. Faculty members 2. The clinical nurses 3. The medical and nursing students

Under which criteria data/document could be used

Access to data or documentation is subject to the following conditions: 1- Use in Future Studies References 2- The future studies

From where data/document is obtainable

Please contact Ali Fakhr-Movahedi Email: alimovi@yahoo.com

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

After emailing Ali Fakhr-Movahedi, email will be answered as soon as possible.

Comments