

# 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

#### Province

Semnan

#### 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

Semnan

### Province

Semnan

### Postal code

3514799442

### Phone

+98 23 3344 1022

### 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

**Full name of responsible person**

Dr. Ali Fakhr-Movahedi

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Associate Professor

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## Person responsible for updating data

### Contact

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**Email**

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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**