# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Nov 2026

## The effect of prevention program on hypothermia on central temperature and chills in women undergoing cesarean section surgery in Ali bin Abitaleb Hospital, Zahedan, 2017

### Protocol summary


**Study aim**

Determining the Effect of Prevention Program on Hypothermia on Central Temperature and Shivering of Women Under Caesarean section at Ali ibn Abitaleb Hospital, Zahedan, 1396

**Design**

This study will be done on 92 candidates for undergoing cesarean section undergoing cesarean section attending a study in the operating room of Ali ibn Abi Talib (Zahedan) Hospital in 1396. They were randomly divided into control and intervention groups.

**Settings and conduct**

46 patients will receive the usual care of the operating room. Then 46 pregnant women will enter the intervention group. The women in the intervention group will be warmed up with a sterilization solution until the temperature reaches 32 ° C. The infusion will be performed at 38 to 40 ° C. And transmitted on the bed after surgery. Central temperature, chills and hemodynamic characteristics of the patient will be measured at 7 times.

**Participants/Inclusion and exclusion criteria**

Criteria for entering the study: 1-Spinal anesthesia 2. Failure to receive corticosteroid 3. Failure to receive non-steroidal anti-ulcer and magnesium sulfate 4. No underlying illness 5. Termination of pregnancy at the time of term Exit criteria: 1. The occurrence of any condition that affects the normal course of anesthesia and surgery 2. Receiving blood during surgery 3. A significant decrease in blood pressure during surgery 4- prolonged surgical time

**Intervention groups**

In this quasi-experimental study, 92 women undergoing cesarean section (emergency and elective surgery) that will undergo a surgical operation in the operating room of the Ali ibn Abi Taleb Hospital in Zahedan, will be targeted and will be included in the study. At first, 46 patients with a candidate for cesarean section who have criteria for entering the study will be selected and will enter the control group. In the routine control group, routine patients will receive routine care of the operating room, including dripping, dripping and infusion of fluids at the operating room temperature, and then transferred to the recovery room after surgery, and will be hospitalized in blanket blankets. Central temperature, blood pressure, pulse, and oxygen saturation of arterial blood, seven times, will be measured. Before starting anesthesia, after induction of anesthesia and before surgery, 30 minutes after surgery, after surgery, At the time of recovery, 0.5 hours and 1 hour after the patient's transfer to the recovery. In this group of patients, the necessary information will be entered into the information registration form on the basis of the data collection tool without any special intervention. After completing the sample size of the control group, 46 pregnant women eligible for inclusion criteria for the intervention group will be selected. Before the beginning, the goals and method of work will be explained to the people and written consent will be obtained from them. The intervention group women, after entering the operating room and placed on the surgical bed, are heated with a sterilized solution until the temperature reaches 32 ° C and eventually drips. Injections of injectable fluids will begin with a doctor prescription (warmed up at 38-40 ° C in the blood vessel). Upon completion of surgery, patients will be transferred from the operation bed to the recovery bed (which has been prepared in the recovery plan after the operation). So, half an hour before the patient is transferred to the recovery room, the bed will be prepared in the standard procedure, and two to three spa tubs will be placed in the bed to welcome the patient's bed at the appropriate temperature of the patient. These patients are similar to those in the control group in 7 cycles. Central temperature, blood pressure, pulse and arterial oxygen saturation were measured 30 minutes after anesthesia,

after induction of anesthesia and before surgery. From the beginning of the surgery, after the completion of the surgery, it will be monitored at recovery time, 0.5 hours and 1 hour after the patient's transfer.

**Main outcome variables**

1. The frequency of incidence of hypothermia in women undergoing cesarean section with spinal anesthesia is different in the intervention group and the control group after the implementation of the hypothermic prevention program. 2. The incidence of shivering in women undergoing cesarean section with spinal anesthesia is different in the intervention group and the control group after the implementation of the hypothermic prevention program.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20171002036505N1**
Registration date: **2017-12-03, 1396/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-03, 1396/09/12**
Update count: **0**

**Registration date**

2017-12-03, 1396/09/12

**Registrant information**

**Name**

Zahra Pishkar Mofrad

**Name of organization / entity**

Zahedan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 54 3344 2481

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**Recruitment status**

**Recruitment complete**

**Funding source**

Zahedan University of Medical Sciences

**Expected recruitment start date**

2017-06-22, 1396/04/01

**Expected recruitment end date**

2018-01-20, 1396/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of prevention program on hypothermia on central temperature and chills in women undergoing cesarean section surgery in Ali bin Abitaleb Hospital, Zahedan, 2017

**Public title**

The effect of warm serum on central body temperature and chills

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Spinal anesthesia No intake of corticosteroid No administration of non-steroidal anti-spasm and magnesium sulfate No underlying disease (thyroid, diabetes, cardiovascular disease and chronic hypertension and preeclampsia) Ending pregnancy at the time of the term (37 to 42 weeks). No fever, addiction, rupture of amniotic sac, polyhydramnios and oligohydroamnios. No constraint for controlling body temperature through tympanic curves.

**Exclusion criteria:**

Occurrence of any situation where the process Natural anesthetic and surgical treatment of the patient. Receiving blood during surgery. Significant loss of blood pressure during surgery. Blood pressure 20% greater than before anesthesia Prolonged surgical time (more than an hour).

**Age**

From **15 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **92**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**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**

Zahedan University of Medical Sciences

**Street address**

No 1 Street of Health Fellowship, Faculty of Nursing Midwifery

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816913396

**Approval date**

2017-06-22, 1396/04/01

**Ethics committee reference number**

IR.ZAUMS.REC.1396.59

## Health conditions studied

### 1

**Description of health condition studied**

Caesarean section

**ICD-10 code**

O82

**ICD-10 code description**

Delivery by elective caesarean section; delivery by emergency caesarean section

## Primary outcomes

### 1

**Description**

Central body temperature

**Timepoint**

Pre-intervention-during intervention-after intervention

**Method of measurement**

Based on degrees C and using the tympanic thermometer

### 2

**Description**

Chill

**Timepoint**

During intervention - after intervention

**Method of measurement**

Based on Crossley classification. Grade 1 = No shivering, Grade 2 = Mild shivering (Hair straightening, Peripheral cyanosis visible without vibration), Grade 3 = Medium shiver (visible muscle tremor in a group of muscles), Grade 4 = Severe chills (Muscle vibration in All muscles of the body)

## Secondary outcomes

### 1

**Description**

Blood pressure

**Timepoint**

Before intervention - during intervention - after intervention

**Method of measurement**

Systolic and diastolic blood pressure using a monitor based on mm of mercury

### 2

**Description**

Pulse rate

**Timepoint**

Before intervention - during intervention - after intervention

**Method of measurement**

Using the monitor and based on the number in minutes

### 3

**Description**

Respiratory rate

**Timepoint**

Before intervention - during intervention - after intervention

**Method of measurement**

Using the monitor and based on the number in minutes

### 4

**Description**

Arterial blood oxygen saturation

**Timepoint**

Before intervention - during intervention - after intervention

**Method of measurement**

Using the monitor and percentage basis

## Intervention groups

### 1

**Description**

This semi- experimental study was performed on 92 candidates for cesarean section by spinal anesthesia referring to the operating room of Ali ibn Abi Talib (Zahedan) Hospital in 1396. 46 patients will receive the usual care of the operating room. The cent

**Category**

Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Operating room of Ali ibn Abitaleb Hospital in Zahedan

**Full name of responsible person**

Zahra pishkar Mofrad

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pishkarz@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Normohammad Bakhshani

**Street address**

Zahedan University of Medical Sciences, Dr. Hesabi Squ.

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fatemeh.bamery71@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Bammeri

**Position**

Senior Inner Surgery / Collaborator

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact**

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**Position**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available