

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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 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)

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Normohammad Bakhshani

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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

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Web page address**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