

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of electric blanket on post-cesarean shivering undergone spinal anesthesia in Bushehr's Persian Gulf hospital.

Protocol summary

Study aim

Evaluation the effect of electric blanket on post-cesarean shivering undergone spinal anesthesia in Bushehr's Persian Gulf hospital.

Design

Clinical trial with control group, with parallel groups design of 112 patients, randomized controlled block, single blind

Settings and conduct

When entering the recovery room of Persian Gulf Hospital in Bushehr, an electric blanket will be placed for the case group and a turned-off electric blanket will be used for the control group and shivering will be recorded before the intervention, 5 minutes and 10 minutes after the intervention. The study was conducted in a blinded manner with the control group using a turned-off electric blanket without patients awareness.

Participants/Inclusion and exclusion criteria

Including criteria: Termination of pregnancy at term (37-42 weeks), spinal anesthesia surgery excluding criteria: vascular diseases, addiction, amniotic membrane rupture, illnesses with symptoms of chills or seizures (Parkinson's disease, epilepsy, etc.), endocrine disorders

Intervention groups

For the case group, an electric blanket is placed when the patient enters the recovery room. And for control group a symbolic electric blanket is used. Control group: The electric blanket will be turned off for this group.

Main outcome variables

Shivering rate (before intervention, 5 minute and 10 minutes after intervention through observation)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190729044364N1**

Registration date: **2019-11-01, 1398/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-01, 1398/08/10**

Update count: **0**

Registration date

2019-11-01, 1398/08/10

Registrant information

Name

parviz azodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3345 0084

Email address

azodi.parviz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of electric blanket on post-cesarean shivering undergone spinal anesthesia in Bushehr's Persian Gulf hospital.

Public title

The effect of electric blanket on post-cesarean shivering

undergone spinal anesthesia in Bushehr's Persian Gulf hospital.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Termination at term pregnancy (37-42 weeks) Surgery by spinal anesthesia

Exclusion criteria:

No vascular disease No addiction No rupture of the amniotic membrane No illnesses that are symptoms of shivering or seizures (Parkinson's disease, epilepsy,) No endocrine disruptions

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block allocation

Blinding (investigator's opinion)

Single blinded

Blinding description

The control group use a turned-off electric blanket which the patient's perception is the opposite.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences- Pardis site, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

7565184345

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.BPUMS.REC.1398.027

Health conditions studied

1

Description of health condition studied

Postoperative shivering of cesarean patients undergoing spinal anesthesia

ICD-10 code

R68.0

ICD-10 code description

Hypothermia, not associated with low environmental temperature

Primary outcomes

1

Description

Shivering rate

Timepoint

Before, 5 minutes after and 10 minutes after intervention

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Case group: A switched-on electric blanket will be placed for this group

Category

Treatment - Devices

2

Description

Control group: The electric blanket will be turned off for this group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Persian Gulf hospital

Full name of responsible person

Parviz Azodi

Street address

Pardis Site of Bushehr University of Medical Sciences,
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Fax**Email**

parviz.azodi@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Boushehr University of Medical Sciences

Full name of responsible person

Gholamreza khamisipour

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Pardis Site of Bushehr University of Medical Sciences,
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ghr.khamisi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Boushehr 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**

Boushehr University of Medical Sciences

Full name of responsible person

Parviz Azodi

Position

faculty member

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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