

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Prevention of Shivering During and Post Cesarean Section with Spinal Anesthesia

Protocol summary

Summary

Shivering is one of the most common intra and postoperative problems with a 20%-60% reported incidence. In addition to patient's discomfort, intra and postoperative hypothermia and shivering interfere with patient's monitoring and can increase oxygen consumption and CO₂ production. Recently α -2 agonists like dexmedetomidine due to central hypothalamic thermoregulation have been shown to be effective in the prevention of intra and postoperative shivering. The aim of this study is to evaluate the effect of dexmedetomidine in prevention of shivering in patients undergoing to cesarean section with spinal anesthesia with suggestion that prophylactic administration of this agent can prevent intra and postoperative shivering or reduce its severity. After obtaining written informed consent for entering to study, 70 pregnant patients scheduled for cesarean section will enrolled in two groups of 35 and receive spinal anesthesia. Case or dexmedetomidine group will be administered 1 μ g/kg dexmedetomidine in 20 ml normal saline immediately after delivery and cord clamping and the control group will receive normal saline as placebo in the same volume. The incidence and severity of intra and postoperative shivering will be checked and recorded according to Crossley and Mahjon scores. Shivering scores equal or higher than 3 will be treated with 0.5 mg/kg IV Meperidine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070210765N9**
Registration date: **2016-12-10, 1395/09/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-10, 1395/09/20

Registrant information

Name

Sousan Rasooli

Name of organization / entity

Alzahra hospital/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Research center, Tabriz University of Medical Sciences

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prevention of Shivering During and Post Cesarean Section with Spinal Anesthesia

Public title

The Effect of Intravenous Dexmedetomidine for Prevention of Shivering During and Post Cesarean Section with Spinal Anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: parturients aged 18-42 years old; patients with ASA class I & II; patients signed informed consent. Exclusion criteria: parturients with ASA class III or high; contraindication for spinal anesthesia; diabetics; preterm labor; hypertension; preeclampsia and eclampsia; allergy; drug or alcohol abuse; cardiovascular disease; respiratory disease; renal and hepatic disease; hypo or hyperthermic disease.

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Ave.

City

Tabriz

Postal code

Approval date

2016-07-04, 1395/04/14

Ethics committee reference number

IR.TBZMED.REC.1395.319

Health conditions studied

1

Description of health condition studied

Hypothermia following anaesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia(Hypothermia following anaesthesia)

Primary outcomes

1

Description

severity of shivering

Timepoint

Intra and postoperative

Method of measurement

Crossley and Mahjon scale

Secondary outcomes

1

Description

Mepidine requirements

Timepoint

Intra and postoperative

Method of measurement

Crossley and Mahjon scale

Intervention groups

1

Description

Intervention or dexmedetomidine group will be administered 1 µg/kg dexmedetomidine in 20 ml normal saline immediately after delivery and cord clamping.

Category

Treatment - Drugs

2

Description

Control group will receive normal saline as placebo in the same volume.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Sousan Rasouli

Street address

Alzahra Hospital, South Artesh Ave, Tabriz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center, Tabriz University of Medical Sciences

Full name of responsible person

Elahi Madarek

Street address

Vice chancellor for reaserch, No 2, Central bulding of Tabriz University of Medical Sciences, Golgasht Ave

City

Tabriz

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

Yes

Title of funding source

Research center, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Sousan Rasouli

Position

Professor of Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty