Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Prophylactic administration of intravenous Paracetamol for control of shivering during and post cesarean section with spinal anesthesia

Protocol summary

Summary

Shivering is a 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 patent's monitoring and can increase oxygen consumption and CO2 production. Recently paracetamol have been used at the end of surgery and 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 paracetamol in prevention of shivering in patients undergoing to cesarean section with spinal anesthesia with suggestion that prophylactic administration of this agent can prevent inta and postoperative shivering or reduce its severity. After obtaining written informed consent for entering to study, one hundred pregnant patients scheduled for cesarean section, will be enrolled in two groups of 50 and received spinal anesthesia. Case group will be administered infusion of 1000 mg paracetamol in 100 cc normal saline immediately after delivery and the control group will receive normal saline as placebo in the same volume. The incidence and severity of inta and postoperative shivering will be checked and recorded according to Crossley and Mahjon scores. Shivering scores equal to or higher than 3 will be treated with 0.5 mg/kg IV petidine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080710765N7**
Registration date: **2015-09-15, 1394/06/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-15, 1394/06/24

Registrant information

Name
Sousan Rasooli
Name of organization / entity
Alzahra hospital/Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1553 9161
Email address
rasoolis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-08-08, 1394/05/17

Expected recruitment end date

2016-08-08, 1395/05/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic administration of intravenous Paracetamol for control of shivering during and post cesarean section with spinal anesthesia

Public title

Prophylactic administration of intravenous Paracetamol for control of shivering during and post cesarean section with spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant womenaged between 16 to 45 years old candidate for elective cesarean section with spinal anesthesia; ASA physical class I or II with informed consent for spinal anesthesia. Exclusion criteria: patients with ASA physical class III or higher; contraindication for administration of NSAIDS and paracetamol; peptic ulcer; coagulopathy; renal failure;hepatic failure; fever; any contraindication for performing spinal anesthesia

Age
From **16 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

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 of Tabriz University of Medical Sciences

Street address
Vice chancellor for Research, No.2 central building of Tabriz University Of Medical Sciences, Golgasht ave

City
Tabriz

Postal code

Approval date
2015-06-24, 1394/04/03

Ethics committee reference number
TBZMED.ERC.1394.275

Health conditions studied

1

Description of health condition studied
Intra and post spinal anesthesia shivering

ICD-10 code
R68.0

ICD-10 code description
Hypothermia, not associated with low enviromental temperature

2

Description of health condition studied
complications of anaesthesia

ICD-10 code
T88.5

ICD-10 code description
Other complications of anesthesia

Primary outcomes

1

Description
Severity of perioperative and postoperative shivering

Timepoint
In recovery every 15 minutes until discharge from recovery

Method of measurement
Crossly and Mahjon five-point scoring system

2

Description
Incidence of intra and post spinal anesthesia shivering

Timepoint
During of surgery and in the recovery room

Method of measurement
visual

Secondary outcomes

1

Description
Need to drug for treatment of shivering

Timepoint
During surgery and in recovery room

Method of measurement
Dose of drug

Intervention groups

1

Description
Intervention group: in this group paracetamol 1000mg in 100 cc normal saline was infused during 15 -20 min after neonatal delivery for prevention of intra and post-operative shivering .

Category
Treatment - Drugs

2

Description
Control group: in this group normal saline iv in same volume intervention group was infused as placebo at

15-20 min after neonatal delivery .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital

Full name of responsible person

Dr. Sousan Rasooli

Street address

Alzahra Teaching Hospital, Artesh Ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tabriz University Of Medical Sciences

Full name of responsible person

Dr. Hassan Soleimanpoor

Street address

Vice chancellor for Research,No.2 Vice chancellor for Research,No.2 central building 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

Vice chancellor for Research, 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

Tabtiz University of Medical Sciences

Full name of responsible person

Sousan Rasouli

Position

Associate Professor, Specialist in Anesthesiology

Other areas of specialty/work

Street address

Alzahra Hospital, Artesh Ave, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3553 9161

Fax

+98 41 3554 4669

Email

rasooli_s@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Sousan Rasooli

Position

Associate Professor, Anesthesiologist

Other areas of specialty/work

Street address

Alzahra Hospital, Artesh Ave, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3553 9161

Fax

+98 41 3556 6449

Email

Rasooli_s@yahoo.com

Web page address

Person responsible for updating data

Contact

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