Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of forced air warming with warm intravenous fluid versus forced air warming alone in preventing hypothermia and shivering in obstetric patients

Protocol summary

Study aim

The objective of this study is to compare methods of forced air warming combined with warm intravenous fluid administration versus forced air warming alone in preventing hypothermia and shivering associated with spinal anesthesia for elective caesarian section.

Design

A preventive, double blinded, randomized controlled clinical trial with a parallel group design of 390 patients, enrolled between January 2023 and July 2023 and a single center study.

Settings and conduct

Core temperature in both groups was recorded using a standard Braun Infrared Thermoscan5 thermometer (IRT 6500) by a resident anesthetist in the operating room unaware of the study protocol being double blind.

Participants/Inclusion and exclusion criteria

included all ASA-I and II female patients presenting for elective caesarian with a gestational age of 37 or more weeks under spinal anesthesia. Excluded patients with pre-maturity, caesarian converted to general anesthesia following spinal administration, patients with fever, cardiac or respiratory disease, patients with PIH (pregnancy induced hypertension) or gestational diabetes mellites and patients unwilling to be included in the study.

Intervention groups

The patients were randomized into Group FWI (forced warming with warm IV fluid) and FWA (forced warming alone).

Main outcome variables

Core body temperature measured in degrees Celsius between Group FWI and Group FWA was 37.34±0.17 degrees Celsius versus 37.34±0.16 degrees Celsius measured pre-spinal administration (p=0.922). It was 36.85±0.09 degrees Celsius versus 36.12±0.10 degrees Celsius 30 minutes after spinal during the procedure between both groups (p<0.001) and was36.84±0.09 degrees Celsius versus 36.11±0.10 degrees Celsius measured 60 minutes in the procedure between both groups (p<0.001)

General information

Reason for update

Acronym

None

IRCT registration information

IRCT registration number: **IRCT20231022059809N1**
Registration date: **2024-03-12, 1402/12/22**
Registration timing: **retrospective**

Last update: **2024-03-12, 1402/12/22**
Update count: **0**

Registration date

2024-03-12, 1402/12/22

Registrant information

Name

Shujaat Hussain

Name of organization / entity

Combined military hospital Rawapindi

Country

Pakistan

Phone

+92 337 9236235

Email address

shujaat169@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

2023-05-22, 1402/03/01

Actual recruitment end date

2023-11-22, 1402/09/01

Trial completion date

2023-11-22, 1402/09/01

Scientific title

Comparison of forced air warming with warm intravenous fluid versus forced air warming alone in preventing hypothermia and shivering in obstetric patients

Public title

Comparison of forced air warming with warm intravenous fluid versus forced air warming alone in preventing hypothermia and shivering in obstetric patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Included all ASA-I and II Patients Female patients presenting for elective caesarian with a gestational age of 37 or more weeks under spinal anesthesia.

Exclusion criteria:

Patients with pre-mature gestational age Caesarian converted to general anesthesia following spinal administration Patients with fever Cardiac or Respiratory disease Patients with PIH (pregnancy induced hypertension) or gestational diabetes mellites Patients unwilling to be included in the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **369**

Actual sample size reached: **390**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization was non-probability consecutive via lottery method and patients were randomized into Group FWI (forced warming with warm IV fluid) and FWA (forced warming alone).

Blinding (investigator's opinion)

Double blinded

Blinding description

Core temperature in both groups was recorded using a standard Braun Infrared Thermoscan5 thermometer (IRT 6500) by a resident anesthetist in the operating room unaware of the study protocol.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee Of Combined Military Hospital Rawalpindi

Street address

Saddar Rawalpindi

City

Rawalpindi

Postal code

00666

Approval date

2023-05-20, 1402/02/30

Ethics committee reference number

492

Health conditions studied

1

Description of health condition studied

Prevention of hypothermia and shivering associated with spinal anesthesia for elective caesarian section.

ICD-10 code

T88.51

ICD-10 code description

Hypothermia following anesthesia

Primary outcomes

1

Description

Core body temperature in both groups before procedure, per-operatively and post-operatively

Timepoint

Core body temperature in both groups’ pre-spinal, 30 and 60 minutes into the procedure and then at 30- and 60-minute intervals in the PACU post-procedure.

Method of measurement

Core temperature in both groups was recorded using a standard Braun Infrared Thermoscan5 thermometer (IRT 6500) by a resident anesthetist in the operating room unaware of the study protocol.

Secondary outcomes

1

Description

Incidence of Shivering due to hypothermia Per-operative

and post-operatively in recovery room

Timepoint

Shivering in both groups' 30 and 60 minutes into the procedure after spinal and then at 30- and 60-minute intervals in the PACU post-procedure.

Method of measurement

Clinical and visual assessment of Shivering alongwith measurement of core body temperature by using standard Braun Infrared Thermoscan5 thermometer (IRT 6500)

Intervention groups

1

Description

Intervention group: forced air warming with warm intravenous fluid in obstetric patients during Surgical procedures after Spinal Anaesthesia to prevent hypothermia

Category

Prevention

2

Description

Control group: forced air warming alone in obstetric patients during Surgical procedures after Spinal Anaesthesia to prevent hypothermia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Combined Military Hospital Rawalpindi

Full name of responsible person
Saddam Hussain

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Combined Military Hospital Rawalpindi

Full name of responsible person
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aqibalishahsyed@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Combined Military Hospital Rawalpindi

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
Combined Military Hospital Rawalpindi

Full name of responsible person
Shujaat Hussain

Position
Postgraduate Resident

Latest degree
Bachelor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

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Saddam Hussain

Position
Resident trainee
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available