

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of Postoperative Electrical Warming Cover and Warmed IV Fluids on Temperature, Shivering and Physiological Indexes in Patient Undergoing General Anesthesia at Post Anesthesia Care Unit(PACU) in Chosen Hospital Affiliated with Social Affair Organization of Tabriz in 1395

#### Protocol summary

##### Summary

This study is a clinical trial that incorporates independent variables being electric overblankets and warm intravenous fluid along with dependent variables including temperature, shivering and physiologic indices. The population in this study includes the patients undergoing general surgery under general anesthesia in 29 Bahman hospital (affiliated to the Social Security Organization). The research samples will be selected in two stages from the target population. In the first stage a purposive sampling will be carried out. In the second stage the patients are assigned into groups one, two and three based on the results of a draw in which patients randomly pick up numbered envelopes. According to the inclusion criteria, eligible patients will be selected and the objectives of the study will be explained to them. Patient will give written informed consent. Parameters evaluated in all three groups are the peripheral and core body temperatures, physiologic indices (systolic and diastolic blood pressures, mean arterial pressure, heart rate and arterial blood oxygen saturation) and intensity of shivering in the post anesthetic care units that will be measured and recorded upon admission of the patient into the operating room, before induction of anesthesia, immediately following the induction and then every 15 minutes until patient is discharged from the recovery unit.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016042527597N1**  
Registration date: **2016-08-04, 1395/05/14**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-08-04, 1395/05/14

##### Registrant information

###### Name

Zakiyeh Imani Sakhlou

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8820 2520

###### Email address

imani.z@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2016-07-15, 1395/04/25

##### Expected recruitment end date

2016-09-20, 1395/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Postoperative Electrical Warming Cover and Warmed IV Fluids on Temperature, Shivering and Physiological Indexes in Patient Undergoing General Anesthesia at Post Anesthesia Care Unit(PACU) in Chosen Hospital Affiliated with Social Affair Organization of

Tabriz in1395

## Public title

Prevention of Postoperative Shivering

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion Criteria: Following criteria will be met for the studied patients: Patients aged between 18 and 60 years; Patients who are candidates for general surgery via anesthesia; Patients without restriction on liquid intake, e.g. excluding patients with acute renal or heart failure; Patients who do not suffer from middle ear infection or from perforation of the eardrum; Patients whose physical status falls in Class 1 or 2, according to the classification of the American Society of Anesthesiologists (ASA). Exclusion Criteria: Patients with core hypothermia or hyperthermia upon intervention; Patients who need blood transfusion during operation; Patients with duration of surgery longer than three hours; Patients who are not extubated or are not transferred to the recovery room post operation at the discretion of the anesthesiologist; Patients who receive vasoconstrictor drugs during surgery; Patient who receive Succinil Colin for induction of anesthesia.

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **54**

## Randomization (investigator's opinion)

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

nursing & midwifery faculty of shahid beheshti university of medical science

##### Street address

shahid beheshti nursing & midwifery faculty-niyayesh intersection- vally asr street-tehran

## City

Tehran

## Postal code

۱۹۸۵۷۱۷۴۴۳

## Approval date

2010-09-23, 1389/07/01

## Ethics committee reference number

IR.SBMU.PHNM.1394.341

## Health conditions studied

### 1

#### Description of health condition studied

postanesthesia shivering

#### ICD-10 code

I98

#### ICD-10 code description

Other disorders of circulatory system in diseases classified elsewhere,

## Primary outcomes

### 1

#### Description

peripheral body temperture

#### Timepoint

upon admission of the patient into the operating room, before induction of anesthesia, immediately following the induction and then every 15 minutes until patient is discharged from the recovery unit

#### Method of measurement

by digital thermometer EmsiG- CT20 made in Germany

### 2

#### Description

core body temperture

#### Timepoint

upon admission of the patient into the operating room, before induction of anesthesia, immediately following the induction and then every 15 minutes until patient is discharged from the recovery unit.

#### Method of measurement

by digital infrared thermometer, EmsiG - CT30 made in Germany to measure the tympanic membrane temperature.

### 3

#### Description

physiologic indices

#### Timepoint

upon admission of the patient into the operating room, before induction of anesthesia, immediately following the induction and then every 15 minutes until patient is discharged from the recovery unit.

#### Method of measurement

measured by Saadat vital signs monitors, Model Alborz-B produced by Pooyandegan Rah Saadat Company of Iran.

## 4

### **Description**

post operative shivering

### **Timepoint**

every 15 minutes at post anesthesia care unit

### **Method of measurement**

the scale described by Crossley and Mahajanto

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

In the experimental group involving electric blankets after surgery, Beurer HD90 blankets (made in Germany) will be used. The blankets come in 130cmx180cm dimensions and could be adjusted for six different temperatures. They feature automatic shutdown system, overheating protection and performance display light. Additionally, these blankets are certified by European Oeko-Tex which approves the textile safety for the consumers. In this group, the blanket will be used after surgery such that it will be prepared and switched on fifteen minutes prior to admission of the patient into the post anesthetic care unit. Upon arrival of the patients into the recovery unit, the blankets will be laid over them and left until the patients are discharged from the recovery unit.

#### **Category**

Prevention

### 2

#### **Description**

In the second experimental group in which warm intravenous fluid is used during surgery, the required liquid intake of the patient will be determined. Once the patient is transferred on to the operating table, the required liquid will be heated to 37 °C under supervision of an anesthesiologist using Biggler Warmer - BW585 assembled in Iran. To connect the intravenous fluid to the warmer set an extension tube is used having the same length for all patients.

#### **Category**

Prevention

### 3

#### **Description**

In the control group, patients will receive routine care. In the studied hospital, patients receive intravenous fluid in ambient temperature during surgery and upon completion of the operation, a usual blanket is laid over patients before transferring them into the recovery room.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

29 Bahman Hospital

##### **Full name of responsible person**

Zakiyeh Imani Sakhlou

##### **Street address**

29 Bahman Hospital, 29 Bahman Boulevard , Tabriz

##### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Ms Simbar

##### **Street address**

Shahid Beheshti Nursing & Midwifery Faculty,  
Niyayesh Intersection, Vali Asr street, Tehran

##### **City**

Tehran

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Mehryar Yoldashkhan

##### **Position**

MSc/board of science

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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*