# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Investigation the effect of intravenous warm fluids on surgery shivering and core temperature in patients undergoing abdominal surgery

## Protocol summary

**Summary**

The purpose of this clinical trial study will be investigated the effect of intravenous warm fluids on surgery shivering and core temperature in patients undergoing abdominal surgery. Seventy non-emergency patient candidate for abdominal surgery referring to operating room of educational hospital (Tohid and Bessat) of Kurdistan University of Medical Sciences investigates in Intervention (n=35) and Control (n=35) groups. The first method of study explores for patients that have inclusion criteria, consent form completed, and randomized to intervention or control groups. Demographic characteristic of patients, Central temperature, arterial oxygen saturation (SPO2), and Systolic and Diastolic pressure, Pulse will measure just in entering the recovery room after surgery. Psychrometer and thermometer model TES made by Taiwan will use. Patients in the intervention group will receive intravenous warm fluids (Ringer) 38 C checked by Warmer. After surgery during entering into recovery room Psychrometer and thermometer will use and patients will receive 5 liter O2 by mask, same kind of blanket used for all patients and monitored. Surgery shivering, core temperature, SPO2, Systolic and Diastolic pressure, Pulse will measure just entering the recovery room and after 30 Min.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201601163311N2**
Registration date: **2016-04-10, 1395/01/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-04-10, 1395/01/22

**Registrant information**

**Name**
Sina Valiee
**Name of organization / entity**
Kurdistan 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**

Kurdistan University of Medical Sciences

**Expected recruitment start date**

2015-12-01, 1394/09/10

**Expected recruitment end date**

2016-05-01, 1395/02/12

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation the effect of intravenous warm fluids on surgery shivering and core temperature in patients undergoing abdominal surgery

**Public title**

Effect of intravenous warm fluids on surgery shivering and core temperature in patients undergoing abdominal surgery

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients undergoing abdominal surgery; Volunteer for research participation; Non-

emergency surgery; Term (37-42 week) pregnancy in cesarean surgery; General or spinal anesthesia; Lack of corticosteroids; NSAIDs; Lack of Magnesium sulfate; Lack of Antihypertensives drugs; Lack of Endocrine disease; Lack of Vascular disease; Lack of Thyroid disease; Lack of Hypertension; Lack of Fever; Lack of addiction
Exclusion criteria: Blood transfusion during surgery; Hypotension during surgery; Patient dissuasion

**Age**
From **18 years** old to **70 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **70**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Kurdistan University of Medical Sciences

**Street address**
Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Kurdistan, Iran.

**City**
Sanandaj

**Postal code**
66177-13446

**Approval date**
2015-11-02, 1394/08/11

**Ethics committee reference number**
MUK.REC.1394.1394/210

## Health conditions studied

### 1

**Description of health condition studied**
surgery shivering

**ICD-10 code**
T88.5

**ICD-10 code description**
Hypothermia following anaesthesia

## Primary outcomes

### 1

**Description**
Shivering

**Timepoint**
Just entering recovery room and after 30 Min

**Method of measurement**
CROSSLEY AND MAHAJAN Scale

### 2

**Description**
Core temperature

**Timepoint**
Just entering recovery room and after 30 Min

**Method of measurement**
Tympanic Thermometer

## Secondary outcomes

### 1

**Description**
SPO2, Systolic and Diastolic pressure, Pulse

**Timepoint**
Just entering recovery room and after 30 Min

**Method of measurement**
Pulse oximeter, Sphygmomanometer

## Intervention groups

### 1

**Description**
Intervention group: Patients in intervention group will received warm fluids (Ringer serum) 38 Celsius after warming and checking by Warmer

**Category**
Prevention

### 2

**Description**
Control group: Patients in control group will received fluids (Ringer serum) with temperature same as room

**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Kurdistan University of Medical Sciences

**Full name of responsible person**

Sina Valiee
**Street address**
Kurdistan University of Medical Sciences, Pasdaran St
**City**
Sanandaj

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kurdistan University of Medical Sciences
**Full name of responsible person**
Mohammad Raman Moloudi
**Street address**
Kurdistan University of Medical Sciences, Pasdaran St
**City**
Sanandaj
**Grant name**
11-8-1394-48319-14
**Grant code / Reference number**
11-8-1394-48319-14
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kurdistan 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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*