

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison of the efficacy of two methods of warming on patient in abdominal surgery on physiologic parameters and shivering in hamedan´s besat hospital in 1392

#### Protocol summary

##### Summary

Objective: Comparison of the efficacy of two methods of warming on patient in abdominal surgery on physiologic parameters and Postoperative shivering. Study design : Stratified random sampling. Study population: patients with abdominal surgery in Besat Hospital in Hamadan. The main criteria for inclusion: patients without underlying diseases such as hypothyroidism, hyperthyroidism, diabetes, hypertension and Cardiovascular disease, no fever, aged between 18 and 65 years, abdominal surgery under general anesthesia up to 3 hours. Main exclusion criteria: the need for blood transfusions during surgery, intra-abdominal infections, Allergy to general anesthetics drugs, Receiving sedation. Sample size: 132 patients. Intervention or interventions studied: in each group, patients will have a warming approach. Intervention Time: In a group 15 minutes before induction of anesthesia, Patient's trunk and lower extremities heated by a warmer and in other group immediately after induction of anesthesia, the patients body covered by a layer of cotton cover and Laminated Fabric to prevent heat loss, design variables before induction, after induction and then every 15 minutes until patient discharge from the recovery will be measured. shivering and grading the severity of shivering in the recovery room by a trained nurse who does not know the type of intervention will be evaluated by an observational tool (Grossely and Mahajan). Primary outcome: changes in physiological parameters and reducing shivering

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013092114722N1**  
Registration date: **2013-10-28, 1392/08/06**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-10-28, 1392/08/06

##### Registrant information

###### Name

Sudabe Asadi

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1262 9801

###### Email address

s.asadi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2013-10-23, 1392/08/01

##### Expected recruitment end date

2014-01-21, 1392/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy of two methods of warming on patient in abdominal surgery on physiologic

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| parameters and shivering in hamedan's besat hospital in 1392                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamadan                                                                                                                                                                                                              |
| <b>Public title</b><br>Comparison of the efficacy of two methods of warming on patient in abdominal surgery on physiologic parameters and shivering in hamedan's besat hospital in 1392                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>City</b><br>Hamadan                                                                                                                                                                                                                                                               |
| <b>Purpose</b><br>Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Postal code</b><br>65178                                                                                                                                                                                                                                                          |
| <b>Inclusion/Exclusion criteria</b><br>Inclusion criteria: abdominal surgery with opening of the peritoneal cavity; Age 18-65 years; abdominal surgery under general anesthesia up to 3 hours; not receiving corticosteroids, nonsteroidal analgesics and anti-hypertensive drugs; Lack of infection; Non-emergency abdominal surgery (elective surgery or urgent); patients without underlying diseases such as hypothyroidism, hyperthyroidism, diabetes, hypertension and Cardiovascular disease. Exclusion criteria: Allergy to drugs used in general anesthesia; The need for blood transfusions during surgery; Patients who require Intravenous fluids during surgery More than the Fluid therapy protocol; Receive a Analgesic and sedative medication before anesthesia induction; Receive a sedative medication in recovery room; patients who have evidence of intra-abdominal infections after opening the abdominal wall. | <b>Approval date</b><br>2013-09-09, 1392/06/18                                                                                                                                                                                                                                       |
| <b>Age</b><br>From 18 years old to 65 years old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Ethics committee reference number</b><br>1689/9/35/16/پ                                                                                                                                                                                                                           |
| <b>Gender</b><br>Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                      |
| <b>Phase</b><br>N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                      |
| <b>Groups that have been masked</b><br>No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                      |
| <b>Sample size</b><br>Target sample size: 132                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                      |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                      |
| <b>Randomization description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                      |
| <b>Blinding (investigator's opinion)</b><br>Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                      |
| <b>Blinding description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                      |
| <b>Placebo</b><br>Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                      |
| <b>Assignment</b><br>Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                      |
| <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                      |
| <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                      |
| <b>Ethics committees</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                      |
| <b>1</b><br><b>Ethics committee</b><br><b>Name of ethics committee</b><br>Hamadan University of Medical Sciences<br><b>Street address</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Health conditions studied</b><br><br><b>1</b><br><b>Description of health condition studied</b><br>Post operative shivering<br><b>ICD-10 code</b><br>t88.5<br><b>ICD-10 code description</b><br>Other complications of anaesthesia                                                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Primary outcomes</b><br><br><b>1</b><br><b>Description</b><br>Shivering<br><b>Timepoint</b><br>Post operative<br><b>Method of measurement</b><br>Visual assessment scale                                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>2</b><br><b>Description</b><br>Blood pressure<br><b>Timepoint</b><br>Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until patient discharge from the recovery<br><b>Method of measurement</b><br>Sphygmomanometer            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>3</b><br><b>Description</b><br>Core body temperature<br><b>Timepoint</b><br>Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until patient discharge from the recovery<br><b>Method of measurement</b><br>Tympanic thermometer |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>4</b><br><b>Description</b><br>Saturation of O2<br><b>Timepoint</b><br>Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until                                                                                                  |

patient discharge from the recovery

**Method of measurement**

Pulse oximetry

**5**

**Description**

Pulse rate

**Timepoint**

Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until patient discharge from the recovery

**Method of measurement**

Hemodynamic Monitor

**6**

**Description**

Respiratory rate

**Timepoint**

Before induction of anesthesia, immediately after induction of anesthesia and then every 15 minutes until patient discharge from the recovery

**Method of measurement**

Enumeration

**Secondary outcomes**

**1**

**Description**

time of shivering

**Timepoint**

Postoperative

**Method of measurement**

Observation

**2**

**Description**

The amount of administered fluids

**Timepoint**

Postoperative

**Method of measurement**

Observation

**3**

**Description**

Duration of surgery

**Timepoint**

Postoperative

**Method of measurement**

The onset of anesthesia until the end of anesthesia

**Intervention groups**

**1**

**Description**

In one group 15 minutes before induction of anesthesia, the patient's trunk and lower extremities is heated by a

heating warmer

**Category**

Prevention

**2**

**Description**

In another group immediately after induction of anesthesia, patients body covered by a layer of cotton cover and laminated fabrics to prevent heat loss

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Hamadan's Besat Hospital

**Full name of responsible person**

Sudabe Asadi, MSc Student in Critical Care Nursing

**Street address**

Besat Hospital, Motahari Blv, Hamadan

**City**

Hamadan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research and Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Heidar Tavailani

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Street, Hamadan

**City**

Hamadan

**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 and Technology, Hamadan  
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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Sudabe Asadi

**Position**

MSc Student in Critical Care Nursing

**Other areas of specialty/work****Street address**

Hamadan University of Medical Sciences, Shahid

Fahmideh Street, Hamadan

**City**

Hamadan

**Postal code****Phone**

+81 12629801

**Fax****Email**

s.asadi@umsha.ac.ir

**Web page address****Email**

nmanuchehrian@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Sudabe Asadi

**Position**

MSc Student in Critical Care Nursing

**Other areas of specialty/work****Street address**

Hamadan University of Medical Sciences, Shahid

Fahmideh Street, Hamadan

**City**

Hamadan

**Postal code****Phone**

+98 81 1262 9801

**Fax****Email**

s.asadi@umsha.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Nahid Manochehrian

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**

Hamadan, Besat Hospital

**City**

Hamadan

**Postal code****Phone**

+98 81 1264 0045

**Fax**

## 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*