

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Evaluation of the Effect of Hypothermia Prevention Program on, Recovery Time, Shivering and Hemodynamic Status in Pediatric Undergoing Orthopedic Surgery Under General Anesthesia

#### Protocol summary

##### Study aim

Determining of the effect of hypothermia prevention program on recovery time, shivering and hemodynamic status in children who are candidates for orthopedic surgery under general anesthesia

##### Design

This study is a randomized, single-blind clinical trial consisting of control and intervention groups. Which will be performed on 60 patients who are divided into two groups of 30 people by simple random method using 60 sealed envelopes. The patient randomly selects an envelope if the letter A is in the intervention group and if it is B in the control group.

##### Settings and conduct

This project was performed in the operating room of Allameh Behloul Gonabadi Hospital and people in the control group received routine care to control the temperature, but in the intervention group, fluids were heated for infusion and the recovery bed was heated. Blinding is done only by the patient and the study will be a blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children undergoing surgery with a minimum of 30 minutes, age 3 to 18 years, general anesthesia, ASA class 1 and 2, body temperature 36 to 37 ° C, Exclusion criteria: significant decrease in blood pressure during surgery, temperature above 37.5 ° C or below 36 ° C, blood and blood products, Drugs other than fentanyl during surgery

##### Intervention groups

In the control group, the child will routinely receive operating room care, including prep, drop, and infusion of operating room temperature fluids. In the intervention group, a heated disinfectant solution up to 32 ° C is used for skin disinfection and 37 ° C fluids are used for intravenous infusion. After surgery, patients are transferred to a recovery bed that was warmed before

the patient was transferred to recovery.

##### Main outcome variables

Determining the incidence of hypothermia, shivering, recovery time, hemodynamic status in both groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200501047254N2**

Registration date: **2022-02-23, 1400/12/04**

Registration timing: **prospective**

Last update: **2022-02-23, 1400/12/04**

Update count: **0**

##### Registration date

2022-02-23, 1400/12/04

##### Registrant information

##### Name

Fatemeh Pouladkhay

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5722 3360

##### Email address

pouladkhay.fatemeh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-06, 1400/12/15

##### Expected recruitment end date

2022-08-06, 1401/05/15

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the Effect of Hypothermia Prevention Program on, Recovery Time, Shivering and Hemodynamic Status in Pediatric Undergoing Orthopedic Surgery Under General Anesthesia

**Public title**  
Evaluation of the Effect of Hypothermia Prevention Program in Children Undergoing Orthopedic Surgery

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children undergoing surgery with a minimum time of 30 minutes Age 3 to 18 years The patients who are candidate for general anesthesia Patients with ASA class 1 and 2 Body temperature 36.5 to 37 ° C No drug addiction Reluctance to continue participating in the project  
**Exclusion criteria:**  
Occurrence of any condition that affects the patient's normal course of anesthesia and surgery, such as excessive bleeding and cardiac arrest during surgery Significant decrease in blood pressure during surgery (20% decrease in blood pressure compared to before anesthesia) Temperatures above 37.5 ° C or below 36 ° C before surgery Receiving blood and blood products during surgery Take corticosteroids Receiving non-steroidal analgesics and magnesium sulfate Prohibition to control body temperature through the tympanic membrane Receiving drugs other than fentanyl during surgery

**Age**  
From **3 years** old to **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **60**

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

**Randomization description**  
The sampling method is simple randomization. For random allocation of participants, 60 envelopes are prepared and in each envelope the names of groups, A or B are placed evenly. Then the patient with the inclusion criteria randomly selects an envelope and according to the name of the group that if A was in the intervention group and if B was in the control group and until the last sample will be done in the same way and the necessary measures for the group Will be done.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**  
This study is a single blind. So that the patient is not aware of the type of measures that will be performed for him, but since the measurement of parameters is done by the researcher, the researcher does not blind.

**Placebo**  
Not used

**Assignment**  
Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

##### Street address

Operating Room Department, School of Paramedical Sciences, Gonabad University of Medical Sciences, Asian Roadside, Gonabad

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793813

#### Approval date

2022-01-24, 1400/11/04

#### Ethics committee reference number

IR.GMU.REC.1400.203

## Health conditions studied

### 1

#### Description of health condition studied

Hypothermia of newborn

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

Hypothermia

#### ICD-10 code

P80

#### ICD-10 code description

Hypothermia of newborn

## Primary outcomes

### 1

#### Description

Hypothermia

#### **Timepoint**

The measurement of the variable in eight shifts will include the following: 5 minutes before the start of anesthesia, 5 minutes after induction of anesthesia and one minute before the start of surgery, 30 minutes after the start of surgery, after the end of surgery, at the beginning of recovery, 30 minutes and 1 hour after transferring the patient to recovery will be monitored

#### **Method of measurement**

Tympan thermometer

### **2**

#### **Description**

Hemodynamic status

#### **Timepoint**

The measurement of the variable in eight shifts will include the following: 5 minutes before the start of anesthesia, 5 minutes after induction of anesthesia and one minute before the start of surgery, 30 minutes after the start of surgery, after the end of surgery, at the beginning of recovery, 30 minutes and 1 hour after transferring the patient to recovery will be monitored

#### **Method of measurement**

Anesthesia monitor

### **3**

#### **Description**

Shivering

#### **Timepoint**

The measurement of the variable at the beginning of recovery, 30 minutes and 1 hour after transferring the patient to recovery will be monitored

#### **Method of measurement**

Mahajan and Crossley criteria will be used to evaluate the incidence of postoperative shivering. The number zero indicates the patient without shivering, the number 1 = mild shivering (hair straightening), the number 2 = moderate shivering (muscle tremors visible in one group of muscles), the number 3 = severe shivering) muscle tremors in more than one group of Muscles but not in the whole body (generalized) and the number 4 - will show very strong vibration (generalized body vibration).

### **4**

#### **Description**

Recovery time

#### **Timepoint**

From the moment of arrival until the patient is discharged from recovery

#### **Method of measurement**

Timer

### **Secondary outcomes**

empty

### **Intervention groups**

### **1**

#### **Description**

Control group: Performing routine care in the operating room to maintain the patient's temperature and prevent hypothermia

#### **Category**

Prevention

### **2**

#### **Description**

Intervention group: In this group, heated solutions up to 32 ° C are used for skin disinfection, heated solutions up to 37 ° C are used for intravenous infusion, and before transferring the patient to recovery, the recovery bed and blanket will be heated by the warmer.

#### **Category**

Prevention

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Allameh Behloul Gonabadi Hospital

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

Fatemeh Pouladkhay

###### **Street address**

Allameh Behloul Gonabadi Hospital, Parstar Blvd., Saadi St., Gonabad, Khorasan Razavi

###### **City**

Gonabad

###### **Province**

Razavi Khorasan

###### **Postal code**

9691797852

###### **Phone**

+98 51 5723 6833

###### **Fax**

+98 51 5723 6160

###### **Email**

pouladkhay.fatemeh@gmail.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

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

Gonabad University of Medical Sciences

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

Dr. Leila Sadeghi Moghadam

###### **Street address**

Deputy of research and technology, Gonabad University of Medical Sciences, Asian Roadside, Gonabad, Khorasan Razavi

###### **City**

Gonabad

###### **Province**

Razavi Khorasan

**Postal code**  
9691793718

**Phone**  
+98 51 5722 3028

**Fax**  
+98 51 5722 3814

**Email**  
pouladkhay.fatemeh@gmail.com

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Gonabad University of Medical Sciences

**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**  
Gonabad University of Medical Sciences

**Full name of responsible person**  
Fatemeh Pouladkhay

**Position**  
Instructor, faculty member of the operating room group

**Latest degree**  
Master

**Other areas of specialty/work**  
Others

**Street address**  
Department of Operating Room, School of Paramedical Sciences, Gonabad University of Medical Sciences, Gonabad, Khorasan Razavi

**City**  
Gonabad

**Province**  
Razavi Khorasan

**Postal code**  
9691793718

**Phone**  
+98 51 5722 3028

**Fax**  
+98 51 5722 3814

**Email**  
pouladkhay.fatemeh@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Gonabad University of Medical Sciences

**Full name of responsible person**  
Fatemeh Pouladkhay

**Position**  
Instructor, member of the operating room group

**Latest degree**  
Master

**Other areas of specialty/work**  
Others

**Street address**  
Department of Operating Room, School of Paramedical Sciences, Gonabad University of Medical Sciences, Gonabad, Khorasan Razavi

**City**  
Gonabad

**Province**  
Razavi Khorasan

**Postal code**  
9691793718

**Phone**  
+98 51 5722 3028

**Fax**  
+98 51 5722 3814

**Email**  
pouladkhay.fatemeh@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**  
Gonabad University of Medical Sciences

**Full name of responsible person**  
Fatemeh Pouladkhay

**Position**  
Instructor, member of the operating room group

**Latest degree**  
Master

**Other areas of specialty/work**  
Others

**Street address**  
Department of Operating Room, School of Paramedical Sciences, Gonabad University of Medical Sciences, Gonabad, Khorasan Razavi

**City**  
Gonabad

**Province**  
Razavi Khorasan

**Postal code**  
9691793718

**Phone**  
+98 51 5722 3028

**Fax**  
+98 51 5722 3814

**Email**  
pouladkhay.fatemeh@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Not applicable  
**Data Dictionary**  
Not applicable  
**Title and more details about the data/document**  
The results of the study will be published along with the working method and executive protocols after the end of the study. Patients' personal information will be kept secure and only the results of the intervention will be

available.  
**When the data will become available and for how long**  
Access period starts from the second half of 1401  
**To whom data/document is available**  
Researchers working in academic and scientific institutions  
**Under which criteria data/document could be used**  
Only the results of the study will be available for other researchers to cite.  
**From where data/document is obtainable**  
Author responsible for the scientific study  
**What processes are involved for a request to access data/document**  
Contact the responsible author via email.  
**Comments**