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 Behlool 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 Behlool Gonabadi Hospital

Full name of responsible person

Fatemeh Pouladkhay

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

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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

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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