

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The effects of warming intravenous fluids on post operative shivering during ENT surgery

#### Protocol summary

##### Summary

Due to the effectiveness of warm intravenous fluids to prevent perioperative hypothermia and thus reduce the shivering caused by hypothermia and considering the importance of controlling postoperative shivering, we decided to study the effectiveness of intravenous warm fluids in the prevention of shivering after ENT surgery. In a double blind randomized controlled clinical trial, 70 patients undergoing ENT surgery will be divided into 2 groups including one receiving of heated fluids (37 ° C) and one receiving liquids at operation room temperature and the core tympanic membrane temperature and postoperative shivering while recovery will be recorded. Patients premedication in both 2 groups will be Similar and General anesthesia will be started with Propofol 2 mg / kg and Atracurium 0.6 mg / kg and for maintenance of anesthesia after intubation 50% of Nitros Oxide and oxygen and Isoflurane 0.7-1 % and infusion 5-8 µg /kg of Remifentanyl will be used. Nasopharyngeal temperature will be recorded using a probe that will be placed through nose after anesthesia induction and will be kept in place until extubation. Primary variable is shivering and secondary variable is O2 saturation. Patients will be monitored for one hour in recovery room and post operational shivering and O2 saturation will be recorded .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201609284005N12**

Registration date: **2016-10-30, 1395/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-10-30, 1395/08/09

##### Registrant information

###### Name

Khosro Kolahdouzan

###### Name of organization / entity

Faculty of Paramedical Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1334 4777

###### Email address

kolahdozank@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of warming intravenous fluids on post operative shivering during ENT surgery

##### Public title

The effects of warming intravenous fluids on post operative shivering during surgery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing ENT surgeries ;

with ASA I or II ; between the ages of 25-70 years old.  
exclusion criteria: hypothermia ;hypertermia ;renal failure ;heart failure ;otitis media

#### Age

From **25 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)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences

##### City

Tabriz

##### Postal code

#### Approval date

2016-08-29, 1395/06/08

#### Ethics committee reference number

1395.628.IR.TBZMED.REC

## Health conditions studied

### 1

#### Description of health condition studied

Shivering

#### ICD-10 code

T88.5

#### ICD-10 code description

Other complications of anesthesia

## Primary outcomes

### 1

#### Description

Shivering

#### Timepoint

Every 10 minute for 1 hour after recovery

#### Method of measurement

Probe for nasopharynx temperature

## Secondary outcomes

### 1

#### Description

O2 Saturation

#### Timepoint

Every 10 minute for 1 hour after recovery

#### Method of measurement

Capnograph

## Intervention groups

### 1

#### Description

Control groups receiving liquids at operation room temperature

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group receiving heated fluids (37 ° C)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Dr Mahmoud Eidy

##### Street address

Emam reza hospital

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Vice Chancellor of Research, Tabriz university of Medical Sciences

##### Street address

Tabriz University of Medical Sciences  
**City**  
Tabriz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tabriz 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**  
Emam Reza Hospital  
**Full name of responsible person**  
Dr Mahmoud Eidy  
**Position**  
Professor of Anesthesia  
**Other areas of specialty/work**  
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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*