Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 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 Atracurrium 0.6 mg / kg and for maintenance of anesthesia after intubation 50% of Nitros Oxaid and oxygen and Isoflurane 0.7-1 % and infusion 5-8 µg /kg of Remifentanil 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

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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 orII ; between the ages of 25-70 years old. exclusion criteria: hypothermia ;hypertermia ;renal failure ;heart failure ;otitis medial

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
Every10 minute for1 hour after recovery

Method of measurement
Probe for nasopharynx temperture

Secondary outcomes

1

Description
O2 Saturation

Timepoint
Every 10 minitue 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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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