Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of normal saline gargling in post intubation sore throat

Protocol summary

Study aim
The effect of normal saline gargling in post intubation sore throat

Design
Randomized clinical trial with two groups of intervention and control, randomized 4-block, phase 3 per 100 patients. Due to the intervention, it is not possible to blind patients. Random randomization is done using SPSS software and syntax.

Settings and conduct
100 patients in the operating room of Imam Hossein (AS) Hospital in Shahroud are divided into intervention and control groups by randomization of 4 blocks, and in the intervention group, a normal saline solution is gargled.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 20 to 50 years, general anesthesia and endotracheal intubation, Class 1 and 2 of anesthesia risk, no airway and intubation problems, patient-related limb surgery,and Maximum duration of anesthesia is 2 hours. Exclusion criteria: Patient dissatisfaction with participation in the study, history of seizures in the patient and history of smoking, drugs, painkillers or psychiatric drugs

Intervention groups
intervention group gargle 40 degrees normal saline solution 3 times, 30 seconds apart for 5 minutes each, which is done half an hour before the operation. There is no intervention in the control group.

Main outcome variables
Age; Gender; Rate of sore throat; Intubation time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210828052308N1**
Registration date: **2021-09-04, 1400/06/13**
Registration timing: **prospective**
Last update: **2021-09-04, 1400/06/13**
Update count: **0**

Registration date
2021-09-04, 1400/06/13

Registrant information

Name
Babak Naghizade

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3239 5054

Email address
babak.ng.1995@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-19, 1400/06/28

Expected recruitment end date
2021-12-19, 1400/09/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of normal saline gargling in post intubation sore throat

Public title
The effect of normal saline gargling in post intubation sore throat

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The age of the person should be between 20 and 50

years For limb surgery, general anesthesia and endotracheal intubation are required has a risk of Class 1 & 2 of anesthesia risk (according to American society of anesthesiologist's classification) The patient does not have airway and intubation problems The patient's operation is related to the limb The duration of anesthesia should not exceed 2 hours.

Exclusion criteria:

The patient does not have personal consent to participate in the study and does not fill in the written form of informed consent The patient has a history of seizures. The patient has a history of smoking, drugs, painkillers or Psychiatric drugs

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After informed concern participants, patients are assigned based on quadruple random blocks in the intervention group (gargling normal saline solution) or control (not gargling normal saline solution). Using SPSS software and random randomization syntax, a table 100 pieces were prepared and according to this table, 100 envelopes were prepared and contained 50 letters A= intervention and 50 letters B=control , will be given to the operating room technician by the person in charge of randomization. Based on this envelope, the participant in the project is assigned to a group and the envelope is discarded.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences and Health Services - 7th of Tir Square - shahroud-semnan-iran

City

shahroud

Province

Semnan

Postal code

3614773947

Approval date

2021-08-23, 1400/06/01

Ethics committee reference number

IR.SHMU.REC.1400.111

Health conditions studied

1

Description of health condition studied

Post operative sore throat

ICD-10 code

J04

ICD-10 code description

Acute laryngitis and tracheitis

2

Description of health condition studied

Post operative sore throat

ICD-10 code

J02

ICD-10 code description

Acute pharyngitis

Primary outcomes

1

Description

Percentage of sore throat after intubation in operating room patients

Timepoint

Evaluation of sore throat intensity at 1, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group are given 40 degrees normal saline solution before surgery. These patients should gargle 3 times, 5 minutes apart, half an hour before the operation. Gargling should be done for 30 seconds each time.

Category

Prevention

2

Description
Control group: There is no intervention in the control group. But the necessary recommendations were also given to this group before and after the operation.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital in Shahroud city
Full name of responsible person
babak naghizade
Street address
Shahroud University of Medical Sciences and Health Services - 7th of Tir Square - shahroud-semnan-iran
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info@shmu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
mohammad hasan emamian
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Shahroud University of Medical Sciences and Health Services - 7th of Tir Square - shahroud - semnan - iran
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+98 23 3239 5009
Email
info@shmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
babak naghizade
Position
general physician intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available