

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of warm Normal saline gargle on sore throat after extubation in open heart surgery patients

Protocol summary

Study aim

Determination effect of warm Normal saline gargle on sore throat after extubation in open heart surgery patients

Design

In this clinical trial study 60 patients who undergoing open heart surgery will be randomly assigned to intervention and control groups.

Settings and conduct

After transfer to the intensive care unit, if the patient's hemodynamic status will be stable and physician orders for remove the endotracheal tube, patients will be extubated. All patients will be extubated in the same way. For both groups, the numerical pain scale will be filled one hour after extubation. Then, intervention group will be gargle 3· cc saline normal solution 40 ° C every 3 hours. There will no intervention for control group. Then, the numerical pain scale will be completed again at 1, 6, 12 and 24 hours after the intervention, for both groups.

Participants/Inclusion and exclusion criteria

Patients undergoing open heart surgery who have the following conditions: Age 30 to 65 years Not having a sore throat and a cold in the last week Ability to communicate Intubation under 30 seconds Malapathy score below 2 No use of cricoid pressure method during anesthesia

Intervention groups

In the first hour after extubation and if patient's condition will be instable in the intensive care unit, the numerical scale of pain for both intervention and control groups would be filled. Then, intervention group will be gargle 3· cc saline normal solution 40 ° C every 3 hours. There will no intervention for control group.

Main outcome variables

sore throat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190311043014N1**

Registration date: **2019-09-13, 1398/06/22**

Registration timing: **prospective**

Last update: **2019-09-13, 1398/06/22**

Update count: **0**

Registration date

2019-09-13, 1398/06/22

Registrant information

Name

Golbahar Iri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3461 2575

Email address

golbahar.iri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of warm Normal saline gargle on sore throat after extubation in open heart surgery patients

Public title

The effect of warm Normal saline gargle on sore throat after extubation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 30-65 years Not having a sore throat and a cold in the last week Ability to communicate Mallampaty score below 2 Don not use of pressure method on cirrhosis during anesthesia Intubation under 30 seconds

Exclusion criteria:

any attempt to reinstall it respiratory infection intubation lasts more than 16 hours in icu bleeding dysrhythmia decreased concsiosness

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into quadruple groups

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Golestan University of Medical Sciences

Street address

Booyeh Nursing and Midwifery Faculty, Falsafi educational Campus, Beginning of Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2019-08-11, 1398/05/20

Ethics committee reference number

IR.GOUMS.RES.1398.177

Health conditions studied**1****Description of health condition studied**

sore throat after the CABG

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Sore throat

ICD-10 code

J02.9

ICD-10 code description

Sore throat

Primary outcomes**1****Description**

Sore throat

Timepoint

Pre intervention; 1,6,12,24 hours after intervention

Method of measurement

Pain Numerical scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: intervention group will be gargle 3·cc saline normal solution 40 ° C every 3 hours. There will no intervention for control group.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmomenin hospital in the kordkoy

Full name of responsible person

Golbahar iri

Street address

Jangal street, Above the water supply

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Yazdi Khadijeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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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

The information is confidential for the privacy of the participants

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The protocol and analyzing method and the results will be published in the form of a report of the project and the scientific paper

When the data will become available and for how long

3 months after submitting the results to the relevant organization

To whom data/document is available

Academic researchers and for nurses who are working in critical care units

Under which criteria data/document could be used

Just to improve the provision of patient care and research work

From where data/document is obtainable

Khadijeh Yazdi

What processes are involved for a request to access data/document

The request is sent by email to be answered by the research team as soon as possible after review

Comments