Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Gorgan University of Medical Sciences
Full name of responsible person
Mohammad Reza Honarvar
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Shast Kola road, Falsafi campus, Deputy of research and technology
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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
Nursery
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Person responsible for updating data

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Anesthesiology
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golbahar.iri@gmail.com

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