Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of the effect of gargling with normal saline and gargling with a tincture of sage and Alcea plants on the incidence of sore throat, cough and hoarseness and the severity of sore throat after endotracheal intubation in patients under general anesthesia.

Protocol summary

Study aim
Determining and comparing the effect of normal saline gargling and tinctured solution of sage and marshmallow plants on the occurrence of sore throat, cough, hoarseness and severity of sore throat after endotracheal intubation in patients under general anesthesia

Design
The clinical trial has a control group, with two parallel groups, three blind strains, randomized, phase 3 on 114 patients. A table of random numbers was used for randomization.

Settings and conduct
This research will be a three-blind clinical trial with three groups, which will be conducted on 114 (5) patients under general anesthesia. A table of random numbers will be used for randomization. The solutions will be prepared in opaque containers with the names A, B and C. Trained research assistants were blinded to the contents of the containers. Therefore, research assistants as well as patients and statistical analysts will be blinded to the groups (triple-blind).

Participants/Inclusion and exclusion criteria
• Patients under general anesthesia with intratracheal intubation • Not having a history of allergy to herbal medicine (especially the components of sage and Alcea plants or other plants from the same family)

Intervention groups
In the first intervention group, gargling 15-20 drops of normal saline, in the second intervention group, gargling 15-20 drops of a tincture of sage and marshmallow diluted in half a glass of water, and in the control group, gargling 15-20 drops of distilled water as a placebo for the patients 2 hours before the start of surgery and immediately before anesthesia (before prescribing any premed or pre-anesthetic medicine to the patient).

Main outcome variables
Tinctured solution of Sage and Alcea Normal saline 0.9% Placebo

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230627058595N1**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**
Update count: **0**

Registration date
2023-07-31, 1402/05/09

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-06, 1402/05/15
Expected recruitment end date
2023-09-06, 1402/06/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of gargling with normal saline and gargling with a tincture of sage and Alcea plants on the incidence of sore throat, cough and hoarseness and the severity of sore throat after endotracheal intubation in patients under general anesthesia.

Public title
Investigating the effect of gargling normal saline and tinctured solution of sage and marshmallow plants on the incidence of sore throat, cough, hoarseness and severity of sore throat after endotracheal intubation in patients under general anesthesia.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
• Patients under general anesthesia with intratracheal intubation • Not having a history of allergy to herbal medicine (especially the components of sage and Alcea plants or other plants from the same family) • Patients with physical condition 1 and 2 (PS or ASA) (either do not have an underlying disease or have a controlled underlying disease.) • Absence of underlying diseases of the oral cavity • Absence of specific diseases related to sore throat, such as viral and bacterial diseases. • Not taking certain drugs, especially NSAIDs, narcotics, benzodiazepines, and neuropsychiatric drugs • Age between 18 and 65 years (5) • Patients who do not have any doubts about difficult intubation during clinical examination. • Abdominal surgery that does not last more than two hours. (14) • Patients do not suffer from chronic cough and allergies
Exclusion criteria:
• The inability of the patient to continue to cooperate for any reason, such as a decrease in the level of consciousness, the death of the patient, etc.• Lack of complete access to the patient• Changing the anesthesia method during surgery for any reason• Performing intubation and laryngoscopy more than once for the patient• Length of laryngoscopy for intubation more than 30 seconds• Patients who have difficult general anesthesia and intubation process.• If the duration of surgery lasts more than 2 hours.• If NGT is used for the patient.• People who use a tracheal tube other than size 5/7 for women and 8 for men.• The patient's unwillingness to continue treatment and cooperation
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **114**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method and description of each method: simple randomization Randomization Unit: Individual Randomization Tool: Like a table of random numbers How to make a random sequence: numbers 1-38 for the first intervention group (normal saline gargle), numbers 39 to 77 for the second intervention group (sage plant and marshmallow tincture) and numbers 78 to 114 will be considered for the control group. . Explanation about concealment: use of opaque sealed envelope with random sequence.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The three studied groups will be named with codes A, B and C, and one of the researchers will keep these codes secret until the end of the data analysis. Therefore, the research assistants (one of the researchers) as well as the patients (participants) and the statistical analyst (data analyst) will be blinded to the groups (triple blind).
Placebo
Used
Assignment
Parallel
Other design features
All patients will be anesthetized in the same way (both in the phase of induction of anesthesia and in the phase of maintnance of anesthesia). Intubation and the anesthesia process will be performed by an anesthetist (under the supervision of an anesthesiologist), who are experts, experienced and professional.The type of anesthesia method, gases and drugs used for anesthesia will be the same for all patients. The size of the endotracheal tube used will be 8 for men and 7.5 for women. (36) All endotracheal tubes will be the same and made of UPVC (polyvinyl chloride).Patients will be told that there are three groups in this study, and you may be randomly assigned to one of the three groups (test or control group) in this study.Sage plant and khatami flower are made into tincture form by Iranian medical doctor, then 20-15 drops diluted in half a glass of water will be given to the patients. (according to the order of a doctor specializing in Iranian medicine)

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical

Sciences

Street address

Hezar Jerib Avenue, Isfahan, Iran

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Isfehan

Postal code

8177769639

Approval date

2023-06-26, 1402/04/05

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.047

Health conditions studied

1

Description of health condition studied

Occurrence of sore throat, cough, hoarseness and throat severity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sore throat severity score based on VAS scale

Timepoint

before discharge from recovery and 6 hours later in the respective inpatient department

Method of measurement

Visual Analogue Scale

2

Description

Percentage of people with sore throat

Timepoint

before discharge from recovery and 6 hours later in the respective inpatient department

Method of measurement

Assessment of the incidence of sore throat from the patient's own statements and observation and recording by a trained assistant of the researcher in the checklist

3

Description

Cough incidence score in the scoring system designed by Harding and McVeigh

Timepoint

before discharge from recovery and 6 hours later in the respective inpatient department

Method of measurement

Harding and McVay scoring system

4

Description

Hoarseness occurrence score in the scoring system designed by Harding and McVey

Timepoint

before discharge from recovery and 6 hours later in the respective inpatient department

Method of measurement

Harding and McVay scoring system

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: In the first intervention group, gargling 15-20 drops of normal saline will be administered to the patients 2 hours before the start of surgery and immediately before anesthesia (before prescribing any premed or pre-anesthetic medicine to the patient). The solution will have a suitable temperature for drinking (25°C). Gargling the solution will be done once for 30 seconds.

Category

Treatment - Drugs

2

Description

The second intervention group: in this group, gargle 15-20 drops of the tincture of sage and marshmallow diluted in half a glass of water for patients 2 hours before surgery and immediately before anesthesia (before prescribing any Primed or pre-anesthetic medicine will be prescribed to the patient. The solution will have a suitable temperature for drinking (25 degrees Celsius). Gargling the solution will be done once and for 30 seconds. The sage plant and jasmine flower will be made into tincture form by an Iranian medical doctor, then 20-15 drops diluted in half a glass of water will be given to the patients. (based on the order of a doctor specializing in Iranian medicine). To prepare the tinctured herbal composition, an Iranian medical specialist made 50 grams of the sage plant (branches and flowers) along with 50 grams of marshmallow plant (roots, leaves, and flowers) in the form of a tincture (hydroalcoholic solution). And it will be combined with a ratio of 1 to 5 (1 for sage plant and marshmallow and 5 for hydroalcohol solution). 100 grams of plants will be kept in 500 grams of hydroalcoholic solution. This mixture is kept in a cool place for two weeks and then strained. We dilute 15 to 20 drops of the tinctured solution in half a glass of water and give it to the patient to gargle.

Category

Treatment - Drugs

3

Description

Control group: Control group: In the control group,

gargling 15-20 drops of distilled water as a placebo will be administered to the patients 2 hours before surgery and immediately before anesthesia (before prescribing any premed or pre-anesthetic medicine to the patient). All solutions will have a suitable temperature for drinking (25 degrees Celsius). Gargling the solutions will be done once for 30 seconds.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
Mehrdad Nowrozi

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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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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research@mui.ac.ir

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Fatemeh Shahnazari

Position
Educator of Nursing and Midwifery Faculty

Latest degree
Master

Other areas of specialty/work
General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Data Dictionary
Not applicable