Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of lavender and rosemary extract on sore throat and Hoarseness caused by endotracheal intubation in patients after Percutaneous Nephrolithotomy

Protocol summary

Study aim
Comparison of the effect of lavender and rosemary extract on sore throat and Hoarseness caused by endotracheal intubation in patients after Percutaneous Nephrolithotomy.

Design
The present study is a randomized clinical trial with control group, with parallel groups, single blind and third phase on 90 Patients who have inclusion criteria that are divided into three groups of treatment with lavender and rosemary extracts and the control group with randomized block method.

Settings and conduct
This study is performed in the urology operating room of Kerman Bahonar Hospital. For men, a tracheal tube with a size (7.5-8) and for women (7.5-7) is used. Also, for all patients, a brand of endotracheal tube is used. A sterile gas impregnated with the studied fluid is inserted into the patient's throat by forceps. These gases are prepared by the relevant anesthesia nurse who entered during the investigation. So that the gases of the intervention groups are impregnated in one group with 3 cc of rosemary syrup with a concentration of 0.5% and the other group with 3 cc of lavender with a concentration of 0.5%; The gases of the control group are also impregnated with 3 cc of distilled water. And patients are transferred to the recovery unit. After the patient awarness, using a VAS scale and a questionnaire related to voice violence by an anesthesia student who was unaware of the grouping, the patient sore throat and voice violence were measured and recorded in recovery 2-6-and24 hours after the patient's extubation.

Participants/Inclusion and exclusion criteria
patients undergoing intubation and located in prone positions

Intervention groups
rosemary group-lavender group-control group

Main outcome variables
sore throat- hoarsness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211124053172N2**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date
2022-01-09, 1400/10/19

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lavender and rosemary extract on sore throat and Hoarseness caused by endotracheal intubation in patients after Percutaneous Nephrolithotomy

Public title

evaluation of the effect of lavender and rosemary extract on sore throat and Hoarseness caused by endotracheal intubation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

age more than 18 year Percutaneous Nephrolithotomy candidate undergoing general anesthesia in prone position ability of communicating and responding to questions using the same brand of endotracheal tube endotracheal size 7.5-8 for men and 7-7.5 for women Mallampati degree 1 and 2 ASA class 1 and 2

Exclusion criteria:

history of sore throat abnormal airway suffering from upper airway infection and respiratory disease like sinusitis, asthma and chronic obstructive disease sensitivity history of lavender and rosemary consumption of anti inflammatory medication over past 2 weeks drug addiction psychopathic

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who met the inclusion criteria were selected by available sampling method and randomly divided into three groups of aromatherapy with lavender, rosemary and control. To compile a random list, the online software https://www.sealedenvelope.com/simple-randomiser/v1/lists will be used, the size of the blocks will be 6 and the two variables (gender / male) and age (Less than 30 years old) will be considered as classes when creating a random list.

Blinding (investigator's opinion)

Single blinded

Blinding description

After being alert and ensuring the patient's ability to communicate in recovery, using the VAS scale and a questionnaire related to voice violence by an anesthesia student who was unaware of the grouping, measures and records sore throat and patient voice violence in recovery 2-6-24hours later.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kerman university of medical sciences

Street address

NO.22,alley 13 , blv jomhouri

City

Kerman

Province

Kerman

Postal code

7618738577

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

IR.KMU.REC.1400.494

Health conditions studied

1

Description of health condition studied

Intubated Patients undergoing Percutaneous Nephrolithotomy

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

sore throat

Timepoint

2-4-24 after extubation

Method of measurement

Visual Analogoue Scale

2

Description

Hoarseness

Timepoint

2-4-24 hours after extubation

Method of measurement
Hoarseness questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After intubation, a sterile gauze impregnated with the studied fluid is placed in the patient's throat with forceps. So that the gases of the intervention groups are impregnated with 3 cc of rosemary syrup with a concentration of 0.5% of Gol Daroo manufacturer.
Category
Prevention

2

Description
Intervention group: After intubation, a sterile gauze impregnated with the studied fluid is placed in the patient's throat with forceps. So that the gases of the intervention groups are impregnated with 3 cc of lavender syrup with a concentration of 0.5% of Gol Daroo manufacturer.
Category
Prevention

3

Description
Control group: The gases of control group are impregnated with normal saline.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar hospital
Full name of responsible person
Atena Samarehfekri
Street address
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Atena Samareh Fekri
Position
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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

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