

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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 awariness, 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

Atena Samareh Fekri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 3491

Email address

atena.samarehfecri@gmail.com

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 jomhour
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 Analogue 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 Samareh Fekri

Street address

NO.22 Alley 13 .jomhoury BLV

City

Kerman

Province

Kerman

Postal code

7618738577

Phone

+98 34 3211 3491

Email

atena.samarehfekri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

The Beginning of Haft Bagh Highway

City

Kerman

Province

Kerman

Postal code

7618738577

Phone

+98 34 3132 5050

Email

abpardakhti@kmu.ac.ir

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

Employee of Kerman University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

No.22 , Alley 13 ,Jomhoury BLV

City

Kerman

Province

Kerman

Postal code

7618738577

Phone

+98 34 3211 3491

Email

atena.samarehfekri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Atena Samareh Fekri

Position

Employee of Kerman University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

No.22 , Alley 13 , Jomhouri BLV

City

Kerman

Province

Kerman

Postal code

7618738577

Phone

+98 34 3211 3491

Email

atena.samarehfekri@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Atena Samareh Fekri

Position

University employee

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

No 22 , Blv jomhouri 13

City

Kerman

Province

Kerman

Postal code

7618738577

Phone

+98 34 3211 3491

Fax

Email

atena.samarehfekri@gmail.com

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