

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effect of licorice-based lozenge on hoarseness/dysphonia

Protocol summary

Study aim

Determining the effect of licorice-based product on hoarseness

Design

Randomized, placebo-controlled, single-blind, parallel-group clinical trial, phase 3 on 80 patients, the card shuffle method was used for simple individual randomization

Settings and conduct

Participants with chief complaint of hoarseness who meet the inclusion criteria, are divided into two groups and coded and listed with the letters A (control group) and B (experimental group) by shuffling the cards. The main drug and placebo are delivered to the relevant group in the renamed box with labels A and B, respectively, so that the participants do not know the name of the drug

Participants/Inclusion and exclusion criteria

entry conditions; - Having a clinical diagnosis of hoarseness - Despite conventional medical treatment, there is no satisfactory recovery - No previous diagnosis of laryngeal mass and malignancy - Absence history of chronic diseases in which licorice is contraindicated -Do not take drugs that interact with licorice No entry conditions; - Diagnosis of mass and malignancy or factors suspected of laryngeal malignancy - Taking drugs that interact with licorice - Presence of hypertension, heart disease with edema, kidney and liver diseases - Pregnancy - Smoking - Hypersensitivity to licorice

Intervention groups

The intervention group will receive 4 tablets containing one gram of licorice extract daily for two weeks; and the control group will receive the placebo, which is completely similar to the herbal product in terms of color, appearance, taste and size, for two weeks with the same number and conditions

Main outcome variables

Hoarseness Score in VHI Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210906052391N1**

Registration date: **2021-11-29, 1400/09/08**

Registration timing: **retrospective**

Last update: **2021-11-29, 1400/09/08**

Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name

Mostafa Solati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3337 2715

Email address

solati.mostafa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

2018-11-03, 1397/08/12

Actual recruitment end date

2021-02-25, 1399/12/07

Trial completion date

2021-02-25, 1399/12/07

Scientific title

Evaluation of the effect of licorice-based lozenge on hoarseness/dysphonia

Public title

licorice in hoarseness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a clinical diagnosis of hoarseness Despite conventional medical treatment, there is no satisfactory recovery No previous diagnosis of laryngeal mass and malignancy Absence history of chronic diseases in which licorice is contraindicated Do not take drugs that seriously interfere with licorice

Exclusion criteria:

Diagnosis of mass and malignancy or factors suspected of laryngeal malignancy Taking drugs that seriously interfere with licorice Presence of hypertension, heart disease with edema, kidney and liver diseases Pregnancy Smoking Hypersensitivity to licorice

Age

From **18 years** old to **55 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Actual sample size reached: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization by shuffling cards In such a way that; 40 cards are considered as the experimental group with the letter B and the same number of cards for the control group with the letter A; Then, by shuffling the cards, a card is taken out and its allocation is recorded. Then the cards are dealt again and another card is taken out. This process continues until a random sequence is reached according to the sample size

Blinding (investigator's opinion)

Single blinded

Blinding description

The intervention group will receive 4 tablets containing one gram of licorice extract daily for two weeks; and the control group will receive the placebo, which is completely similar to the herbal product in terms of color, appearance, taste and size, for two weeks with the same number and conditions

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Faculty of Iranian Medicine, Intersection of Hafez St. with Behesht St

City

Tehran

Province

Tehran

Postal code

1114733311

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

IR.IUMS.REC.1397.069

Health conditions studied

1

Description of health condition studied

Hoarseness

ICD-10 code

R49.0

ICD-10 code description

Dysphonia Abductor dysphonia; Chronic hoarseness; Difficulty speaking; Dysphonia, abductor; Hoarse; Hoarseness; Hoarseness, chronic; Plica dysphonia ventricularis; Ventricular dysphonia; Voice disorder, dysphonia; Hoarseness

Primary outcomes

1

Description

The effect of hoarseness on daily life, before the intervention

Timepoint

At the beginning of the study, before the intervention

Method of measurement

Mean score of quality of life using voice disability index (VHI) questionnaire before intervention

2

Description

The degree of change in hoarseness and its effect on daily life after the intervention

Timepoint

14 days after the intervention

Method of measurement

Mean score of quality of life using vocal disability index (VHI) questionnaire after intervention

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group takes 4 lozenges one after another in one meal every day. Without consuming it with water or food. The duration of use is 14 days. Each tablet contains 250 mg of licorice extract, so the total consumption of licorice extract will be one gram per day. This drug has been prepared as a pilot research in collaboration with Toubia Green Gold Institute in the tablet factory

Category

Treatment - Drugs

2

Description

Control group: The control group takes 4 placebo lozenges one after the other in one meal every day. Without consuming it with water or food. The duration of use is 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of the Faculty of Iranian Medicine

Full name of responsible person

Mostafa Solati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Soleimani

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mostafa Solati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All data related to biographical information and self-reported scores of patients can be shared with the potential voice disability questionnaire after identifying individuals.

When the data will become available and for how long

6months after the publication of the results

To whom data/document is available

Everyone can access the data

Under which criteria data/document could be used

There are no other special conditions for accessing the documents

From where data/document is obtainable

Applicants for correspondence can contact Dr. Mostafa Solati via the following email address.

Solati.Mostafa@yahoo.com

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

After sending the request via email, the request will be reviewed and answered within a week or so

Comments