

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of herbal composition "Taryaqe Vabaei" on the severity of symptoms of patients with upper respiratory infections with cold-like symptoms: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of herbal composition "Taryaqe Vabaei" on the severity of symptoms of upper respiratory infection with cold-like symptoms

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 66 patients. The rand function of Excel software was used for randomization

Settings and conduct

A randomized clinical trial with a control group and double-blind (project researcher physician and participants) on 66 people with upper respiratory infections with cold-like symptoms, in the age range of 30 to 50 years, referring to health centers under Covering Neyshabor city affiliated to Neyshabor University of Medical Sciences. After random allocation, in the intervention group, the capsule of the "Taryaqe Vabaei" herbal combination (two 500 mg capsules per day for 14 days) will be delivered in the relevant packaging. Clinical symptoms will be evaluated based on standard VAS questionnaire and clinical information checklist. In the control group, placebo capsules similar to the original drug in terms of shape, color and size are prescribed in the respective packaging.

Participants/Inclusion and exclusion criteria

Age 30 to 50 years, presence of mild and outpatient symptoms of upper respiratory infection, no history of allergy to herbal medicines in the composition

Intervention groups

Patients with upper respiratory infections with cold-like symptoms

Main outcome variables

Severity of symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231025059862N1**

Registration date: **2023-11-06, 1402/08/15**

Registration timing: **prospective**

Last update: **2023-11-06, 1402/08/15**

Update count: **0**

Registration date

2023-11-06, 1402/08/15

Registrant information

Name

Mehdi Zarvandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3325 1653

Email address

dr.zarvandi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of herbal composition "Taryaqe Vabaei" on the severity of symptoms of patients with upper respiratory infections with cold-like symptoms: a randomized controlled clinical trial

Public title

Investigating the effect of "Taryaqe Vabaei " in cold-like infections

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30 to 50 years, , presence of mild and outpatient symptoms of upper respiratory infection,

Exclusion criteria:

History of allergy to herbal medicines in the composition, History of diabetes History of hypokalemia,cardiovascular disease or digoxin use, History of hypothyroidism Pregnancy and breastfeeding Participation in another clinical study of upper respiratory infection with cold-like symptoms in the 2 months before entering the present study.

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples to be studied will be selected by available sampling from among those who refer to the mentioned centers. Then these samples will be divided into two groups by simple randomization method. First, according to the number of samples in each group, the letters A (intervention group) and B (control group) are written in the envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to the type of study (double-blind), blinding is done for the research doctor and the participants

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Neyshabur University of Medical Sciences

Street address

17 Shahrivar St. 29 Number 5

City

Neyshabur

Province

Razavi Khorasan

Postal code

4917813171

Approval date

2023-10-18, 1402/07/26

Ethics committee reference number

IR.NUMS.REC.1402.019

Health conditions studied

1

Description of health condition studied

upper respiratory infections

ICD-10 code

J00

ICD-10 code description

Acute upper respiratory infections

2

Description of health condition studied

Upper respiratory infections

ICD-10 code

J00

ICD-10 code description

Acute nasopharyngitis [common cold]

Primary outcomes

1

Description

Severity of symptoms of upper respiratory infection with cold-like symptoms

Timepoint

On day zero, at the end of the first week and at the end of the second week

Method of measurement

Visual Analogue Scale standard questionnaire and clinical information checklist

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, while receiving the relevant standard treatment, the capsule of herbal "Taryaqe Vabaei" for epidemics containing the extract of yellow patience, myrrh and saffron along with the method of use (two capsules of 500 mg per day for 14 days) in the packaging made by Niak Pharmaceutical Company, delivered by the company are given.

Category

Treatment - Drugs

2

Description

In the control group, a placebo capsule (two 500 mg capsules containing starch per day for 14 days) similar to the original drug in terms of shape, color and size in the packaging prepared by Niak Pharmaceutical Company, is prescribed and treated similarly to the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health-treatment centers of Neishabur city, under the coverage of Neishabur University of Medical Sc

Full name of responsible person

Saeed SepehriKia

Street address

No. 5, 17 Shahrivar St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neyshabour University of Medical Sciences

Full name of responsible person

Vice President of University Research and Technology

Street address

No. 5, 17 Shahrivar St

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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

Neyshabour 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

Neyshabour University of Medical Sciences

Full name of responsible person

Saeed SepehriKia

Position

Resident

Latest degree

Master

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mehdi Zarvandi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Shahid Sayad Shirazi 27, Naranj building, 3rd floor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers, pharmacists and doctors

Under which criteria data/document could be used

For research and medical purposes

From where data/document is obtainable

Neyshabur University of Medical Sciences

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

Registration of application - processing - non-contradiction with university rules and research ethics - disposal

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Mehdi Zarvandi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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