

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of “Zofa” herbal syrup in hospitalized patients with post infection cough: A Double Blind Randomized Clinical Trial

Protocol summary

2021-05-18, 1400/02/28

Study aim

Evaluation of “Zofa” herbal syrup in hospitalized patients with post infection cough

Design

A Double Blind Randomized Clinical Trial with 100 patients

Settings and conduct

Hospitalized patients who meet criteria will be chosen. All demographic data will be collected. patients will be in two different group randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: hospitalized patient with consent form/ age 18 to 75 year/ cough after infection diagnosed by physician. Exclusion criteria: participating in another study/ pulmonary disease/ hemoptysis/ rhinitis and allergy/ DM 1&2/ seizure/ receiving venlafaxin,phenytoin, phenobarbital, gentamicin/ GERD/ smoking/ hypersensitivity to herbal medicine/ pregnancy and lactation/ use of ACEI which may cause cough

Intervention groups

Intervention group: receiving 10cc Zofa syrup TDS for 1 week Control group: receiving 10cc placebo syrup TDS for 1 week

Main outcome variables

relieving cough

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210508051215N1**

Registration date: **2021-05-18, 1400/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-18, 1400/02/28**

Update count: **0**

Registration date

Registrant information

Name

Marziyeh Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2321

Email address

heydarimarziyeh89@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-02, 1400/02/12

Expected recruitment end date

2021-07-03, 1400/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of “Zofa” herbal syrup in hospitalized patients with post infection cough: A Double Blind Randomized Clinical Trial

Public title

Evaluation of "Zofa" herbal syrup in cough

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All hospitalized patient with post-infection cough

Exclusion criteria:

Participating in another study Known case of DM 1 & 2,

seizure, pulmonary disease like asthma and COPD Drug history of phenytoin, phenobarbital, gentamicin and venlafaxin Symptoms like hemoptysis which may have special diagnosis Pregnancy and lactation Drug which may cause cough like ACEI History of Rhinitis and allergy, GERD, smoking Hypersensitivity to any ingredient of herbal syrup

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be in two group which include 50 person by use of randomized list provided by randomization scheme of permuted blocks way.

Blinding (investigator's opinion)

Double blinded

Blinding description

All syrups are coded. All participants, nurses, physician, investigator, analyzer are blinded and did not know which one is drug or placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

Qods St

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-05-01, 1400/02/11

Ethics committee reference number

IR.TUMS.TIPS.REC.1400.026

Health conditions studied

1

Description of health condition studied

post infection cough

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

cough score in visual analogue scale

Timepoint

Day 1,2,7,14

Method of measurement

visual analogue scale

2

Description

cough score in simplified cough score

Timepoint

Day 1,2,7,14

Method of measurement

Simplified cough score

3

Description

Score in cough symptom score

Timepoint

Day 1,2,7,14

Method of measurement

Cough symptom score

Secondary outcomes

1

Description

Data laboratory changes

Timepoint

Daily

Method of measurement

Data laboratory from blood sample

Intervention groups

1

Description

Intervention group: the coded syrup will be administrated each 8h 10 cc for 1 week

Category

Treatment - Drugs

2

Description

Control group: the coded syrup will be administrated each 8h 10 cc for 1 week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeinin hospital

Full name of responsible person

Marziyeh Heydari

Street address

Keshavarz Blv

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Postal code

14197 33141

Phone

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Email

heydarimarziyeh89@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mojgan Karbakhsh Davari

Street address

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Phone

+98 21 8889 6696

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mkarbakhsh@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Marziyeh Heydari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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

Tehran University of Medical Sciences

Full name of responsible person

Marziyeh Heydari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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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