Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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
2021-05-18, 1400/02/28

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, analyzor 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
City
Tehran
Province
Tehran
Postal code
14197 33141
Phone
+98 21 6119 0000
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
Qods St
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8889 6696
Email
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
Street address
No. 218, Keshavarz Blv
City
Tehran
Province
Tehran
Postal code
1417763388
Phone
+98 21 6119 2321
Fax
Email
heydarimarziyeh89@gmail.com

Person responsible for scientific 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
Street address
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Tehran
Province
Tehran
Postal code
1417763388
Phone
+98 21 6119 2321
Fax

Email
heydarimarziyeh89@gmail.com

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
Medical Pharmacy

Street address
No. 218, Keshavarz Blv

City
Tehran

Province
Tehran

Postal code
1417763388

Phone
+98 21 6119 2321

Email
heydarimarziyeh89@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