Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Efficacy of Jinhua Qinggan Granules (JHQG) for the Treatment of Upper Respiratory Infection: A Clinical Trial

Protocol summary

Study aim

evaluate the efficacy of Jinhua Qinggan granules in symptomatic patients infected with Upper Respiratory Tract Infections

Design

This clinical trial is a randomized, double-blind, phase 3, placebo-controlled study on 200 patients

Settings and conduct

The efficacy of Jinhua Qinggan granules will evaluate in symptomatic patients infected with Upper Respiratory Tract Infections. Patients will be selected in Hamadan city. This study is double-blind and the researcher, clinical staff and analyst will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age Between of 18-65 years; Body Temperature between 37.5ºC -39; Having 3 or more symptoms: Nasal Congestion, Rhinorrhea, Sore and/or scratchy throat, sneezing, headache, muscle or body aches or malaise; The subject has signed the informed consent form. Exclusion criteria: Other Respiratory diseases or acute and chronic nasal diseases or abnormal nasal mucosal function after nasal surgery or nasopharyngeal radiotherapy; Severe primary health conditions associated with cardiovascular, cerebrovascular, pulmonary, hepatic, renal, endocrine and hematological diseases, hematopoietic system and mental illness or serious diseases affecting their survival, such as cancer or AIDS; With severe cardiopulmonary dysfunction, cardiopulmonary insufficiency; Allergic individuals; Pregnant women, and lactating women; subjects who are not suitable for the clinical trial based on investigators' judgment; Subjects who consume alcohol.

Intervention groups

There are two groups in the study: the treatment group that receives herbal medicine and the control group that receives placebo

Main outcome variables

Nasal Congestion; Rhinorrhea (runny nose); Sneezing; Sore throat; Scratchy throat; Cough; Malaise (low energy or tiredness); Muscle or body aches; Headache; Chills or Shivering; Hoarseness; Anorexia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210913052453N2**
Registration date: **2022-06-21, 1401/03/31**
Registration timing: **prospective**

Last update: **2022-06-21, 1401/03/31**
Update count: **0**

Registration date

2022-06-21, 1401/03/31

Registrant information

Name

hemen moradi-sardareh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3313 2015

Email address

hemen.moradi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Jinhua Qinggan Granules (JHQG) for the Treatment of Upper Respiratory Infection: A Clinical Trial

Public title

Treatment of Upper Respiratory Infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body Temperature > 37.5ºC and highest point <39ºC within 24hours of enrollment, Within 12 hours of screening, three or more of the following main symptoms: Nasal Congestion, Rhinorrhea, Sore and/or scratchy throat, sneezing, headache, muscle or body aches, or malaise. The subject has signed the informed consent form.

Exclusion criteria:

Other Respiratory diseases or acute and chronic nasal diseases or abnormal nasal mucosal function after nasal surgery or nasopharyngeal radiotherapy Severe primary health conditions associated with cardiovascular, cerebrovascular, pulmonary, hepatic, renal, endocrine and hematological diseases, hematopoietic system and mental illness or serious diseases affecting their survival, such as cancer or AIDS With severe cardiopulmonary dysfunction, cardiopulmonary insufficiency Subjects, who were treated with other Chinese and western drugs (including drugs for common cold, antiviral, antibiotics, and similar traditional Chinese medicine) and antipyretic and analgesic drugs within 6 hours before enrollment. Allergic individuals and those who are known to be allergic to experimental drugs. Pregnant women, and lactating women Subject, who has participated in the past 1 month in another clinical study. Subjects who are not suitable for the clinical trial based on investigators' judgment. Subjects who consume alcohol.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **1000**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method we use random sequence generation using web randomization. Which is a type of Permuted block randomization. The output it gives us is an Excel file. And inside the Excel file, how each person enters which block is completely randomly determined. For example, if the block size is four, then the first four participants enrolled form the first block, and the next four form the next block, and so on. Randomization occurs within the blocks, so with blocks of size four there are six possible patterns: AABB, ABAB, ABBA, BAAB, BABA, and BBAA. Each block will randomize according to one of these six patterns, with the patterns chosen randomly and, generally, independently from block to block.

Blinding (investigator's opinion)

Double blinded

Blinding description

The test drug should be coded according to the randomization list and the subject will be assigned to the group strictly according to the number of investigational drugs. After the final selection, subject number will be assigned to eligible 1000 subjects for identification i.e. 001, 002, ... 1000. All subjects will receive the corresponding treatment according to the distribution table (the trial drug, the control drug distributed according to the proportion of (3;1). The drug number will be kept same as the CRF number.

Placebo

Used

Assignment

Parallel

Other design features

The study will be conducted in 5 countries and each country includes a sample of 200 people

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethic committees of Asadabad school of medical sciences

Street address

Hamadan Province, Assadabad County, Imam Khomeini Square, at the beginning of Rafsanjani St., the headquarters of the Faculty of Medical Sciences and Health Services of Assadabad

City

Asadabad

Province

Hamadan

Postal code

6541843189

Approval date

2022-05-25, 1401/03/04

Ethics committee reference number

IR.ASAUMS.REC.1401.001

Health conditions studied

1

Description of health condition studied
Acute nasopharyngitis
ICD-10 code
J00
ICD-10 code description
Acute nasopharyngitis [common cold]

2

Description of health condition studied
Acute sinusitis
ICD-10 code
J01
ICD-10 code description
Acute sinusitis

3

Description of health condition studied
Acute pharyngitis
ICD-10 code
J02
ICD-10 code description
Acute pharyngitis

4

Description of health condition studied
Acute tonsillitis
ICD-10 code
J03
ICD-10 code description
Acute tonsillitis

5

Description of health condition studied
Acute laryngitis and tracheitis
ICD-10 code
J04
ICD-10 code description
Acute laryngitis and tracheitis

6

Description of health condition studied
Acute obstructive laryngitis [croup] and epiglottitis
ICD-10 code
J05
ICD-10 code description
Acute obstructive laryngitis [croup] and epiglottitis

7

Description of health condition studied
Acute upper respiratory infections of multiple and unspecified sites
ICD-10 code
J06
ICD-10 code description
Acute upper respiratory infections of multiple and unspecified sites

Primary outcomes

1

Description
Curative Rate Evaluation
Timepoint
Measure the body temperature by treatment day 2/3/4/5
Method of measurement
In this study, data are obtained based on clinical and laboratory studies

2

Description
Lab tests (Improvement in Lymphocyte count, CRP, ESR levels etc.)
Timepoint
Measurements will be taken before and after the treatment period
Method of measurement
In this study, data are obtained based on clinical and laboratory studies

Secondary outcomes

1

Description
Recovery time: disappearance of all symptoms of more than 24 hours
Timepoint
Measurements are performed before and after treatment
Method of measurement
By questionnaire, clinical and laboratory

2

Description
Defervescence rate (body temperature < 37 °C for more than 24 hours).
Timepoint
Measurements are performed before, 2/3/4/5 after beginning of treatment, and after treatment
Method of measurement
By questionnaire, clinical and laboratory

3

Description
Defervescence start time: (Time between treatment and body temperature decrease 0.5°C for more than 24h).
Timepoint
Measurements are performed before and after treatment
Method of measurement
By questionnaire, clinical and laboratory

4

Description
Recovery time of individual symptom
Timepoint
Measurements are performed before and after treatment
Method of measurement
By questionnaire, clinical and laboratory

5

Description
Disappearance of individual symptom (symptom score reach 1 or 0 for more than 24 hours)
Timepoint
Measurements are performed before and after treatment
Method of measurement
By questionnaire, clinical and laboratory

6

Description
The quality of life of the product will be assessed by using the patient's Quality of Life Assessment Questionnaire (QOL).
Timepoint
Measurements are performed before and after treatment
Method of measurement
By questionnaire, clinical and laboratory

Intervention groups

1

Description
Intervention group: The treatment group will take Jinhua Qinggan granules. Jinhua Qinggan granules were invented during the H1N1 pandemic in 2009 (SFDA Approval number: Chinese medicine Z20160001); the prescription was designed by the Chinese and Western medical experts organized by the Beijing Administration of Traditional Chinese Medicine. Jinhua Qinggan granules doage: 5g/sachet; 1 sachet each time, 3 times daily aftermeal, dissolve in boil water. The course of treatment is 5 days, and the visit points are set on the 1st and 5th day, in which the 5th day is follow-up. Patients will be assessed by using 4-category ordinal scale and clinical signs and symptoms on 2nd, 3rd, 4th, and 5th day. All effectiveness and safety inspection items will be done once before the trial and once at follow-up point i.e. 5th day. In case of any new abnormality or abnormality aggravation after the treatment, should be followed up until normal or stable
Category
Treatment - Drugs

2

Description
Control group: The Placebo control group shall receive JHQG Granules simulation (placebo) agent. The JHQG Placebo should be administered orally according to the recommended time and dose.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Asadabad school of medical sciences
Full name of responsible person
Hemen Moradi-Sardareh
Street address
Imam Khomeini Square, at the beginning of Rafsanjani St., Asadabad Faculty of Medical Sciences and Health Services
City
Asadabad
Province
Hamadan
Postal code
6541843189
Phone
+98 81 3312 2499
Email
hemen.moradi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Asadabad University of Medical Sciences
Full name of responsible person
Hosein Effatpanah
Street address
Imam Khomeini Square, At the beginning of Rafsanjani St., Asadabad Faculty of Medical Sciences and Health Services
City
Asadabad
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Postal code
6541843189
Phone
+98 81 3312 2499
Email
hoseineffatpanah@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Asadabad University of Medical Sciences
Proportion provided by this source
5
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

2

Sponsor

Name of organization / entity

Ju Xie Chang (Beijing) Pharmaceutical Co. Ltd

Full name of responsible person

Prof. Dr M. Raza Shah

Street address

Jingtang Kejiyuan Zhong, Street No.# 01, Daxing district, Beijing 102606, China

City

Beijing

Postal code

-

Phone

+86 10 8437 6363

Email

yang.esports@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ju Xie Chang (Beijing) Pharmaceutical Co. Ltd

Proportion provided by this source

95

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

CN

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Asadabad University of Medical Sciences

Full name of responsible person

Hemen Moradi-Sardareh

Position

Assistant Professor, Asadabad School of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Assadabad city, Imam Khomeini Square, at the beginning of Rafsanjani street, the headquarters of the Faculty of Medical Sciences and Health Services of Assadabad

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Ebrahim Nadi

Position

Professor of Internal Medicine

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Asadabad University of Medical Sciences

Full name of responsible person

Hemen Moradi-Sardareh

Position

Assistant Professor, Asadabad School of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Imam Khomeini Square, at the beginning of Rafsanjani St., Asadabad Faculty of Medical Sciences and Health Services

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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
The purpose of this study is to publish the data in the form of an article that includes all the information including the results, working method, and consent form.
When the data will become available and for how long
Access started from 1402
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
If you use the method and results of this study, it is necessary to refer to this article and use it
From where data/document is obtainable
Hemen moradi-sardareh
What processes are involved for a request to access data/document
We will contact them as soon as possible after the request
Comments