

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The preventive effect of short-term administration of a herbal combination of jujube and chamomile on the symptoms of intermittent mild asthma in children under 7 years old with viral cold.

Protocol summary

Study aim

The preventive effect of short-term administration of a herbal combination of jujube and chamomile on the symptoms of intermittent mild asthma in children under 7 years old with viral cold.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized

Settings and conduct

50 eligible children are divided into 2 groups. Patients admitted to the pediatric asthma and allergy clinic of Akbar Hospital, in addition to their standard treatment, receive 0.5 cc herbal drops or a placebo made by a pharmacist for 2 weeks. They receive every 8 hours per kilogram of the child's weight. Follow-up is done on the 3rd and 7th and 14th days by phone and according to the checklist.

Participants/Inclusion and exclusion criteria

Children under 7 years of age, confirmation of the diagnosis of mild intermittent asthma by a pediatric immunologist based on the GINA guidelines, having an acute respiratory viral infection.

Intervention groups

In a double-blind clinical trial study, children with mild intermittent asthma will be included in the study if they meet the inclusion criteria and do not have the exclusion criteria. 50 eligible children will be divided into 2 groups. In addition to their standard treatment, the patients will receive herbal drops for up to 2 weeks. Or they receive the placebo made by the pharmacist at the rate of 0.5 cc per kilogram of the child's weight every 8 hours. Follow-up is done on the 3rd and 7th and 14th days by phone and according to the checklist.

Main outcome variables

The amount of daily cough, the amount of nighttime cough, the amount of salbutamol used, the need for oral corticosteroids, the need for a doctor's visit, the need for

hospitalization.

General information

Reason for update

making a minor change in the title and method, so that it can show a more specific concept of the research.

Acronym

IRCT registration information

IRCT registration number: **IRCT20151230025772N11**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-05, 1402/07/13**

Update count: **1**

Registration date

2022-12-31, 1401/10/10

Registrant information

Name

Seyyed Abbas Zojaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2717

Email address

zojajia881@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The preventive effect of short-term administration of a herbal combination of jujube and chamomile on the symptoms of intermittent mild asthma in children under 7 years old with viral cold.

Public title

The preventive effect of short-term administration of a herbal combination of jujube and chamomile on the symptoms of intermittent mild asthma in children under 7 years old with viral cold.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

children under 7 years old Confirmation of the diagnosis of mild intermittent asthma by a pediatric immunologist based on the GINA guidelines Having an acute respiratory viral infection

Exclusion criteria:

Bacterial respiratory infection Asthma exacerbation History of allergy to herbal medicines Congenital abnormalities Any underlying disease Lack of appropriate compliance for drug treatment Failure to refer for follow-up

Age

To 7 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. Sealed envelopes are used to hide the treatment. Random numbers between 0 and 1 will be generated using the calculator. Envelopes that receive codes between 0 and 0.5 will be filled with placebo and envelopes that receive codes between 0.5 and 1 will be filled with medicine. In this way, the envelopes are arranged in a random order. The envelopes are thick and opaque. Patients and physicians do not know the content of the codes until the end of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, double-blind sealed packages were used to hide the treatment from doctors and patients. The doctor and patients did not know the contents of the drug or placebo package. The drug and placebo are given to the

patient in the same package

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University -Mashhad Branch

Street address

Shahinfar Medical School . Imam Khomeini Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9187147578

Approval date

2022-07-27, 1401/05/05

Ethics committee reference number

IR.IAU.MSHD.REC.1401.151

Health conditions studied**1****Description of health condition studied**

asthma

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes**1****Description**

cough

Timepoint

first visit , the third day, the seventh day, the fourteenth day

Method of measurement

Number of coughs per day/cough severity based on visual analog scale

2**Description**

nighttime wakeup due to coughing

Timepoint

first visit , the third day, the seventh day, the fourteenth

day
Method of measurement
amount

3

Description

The amount of salbutamol usage

Timepoint

first visit , the third day, the seventh day, the fourteenth day

Method of measurement

number of puff per day

4

Description

oral corticosteroid need

Timepoint

first visit , the third day, the seventh day, the fourteenth day

Method of measurement

has/doesn't have

5

Description

specialist visit requierment

Timepoint

the third day, the seventh day, the fourteenth day

Method of measurement

has/doesn't have

6

Description

need for hospital admission

Timepoint

the third day, the seventh day, the fourteenth day

Method of measurement

has/doesn't have

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 25 children with mild intermittent asthma will be included in the study if they meet the inclusion criteria and do not have the exclusion criteria. In addition to their standard treatment, patients receive up to 2 weeks herbal drops containing chamomile and jujuba, prepared by a pharmacist and with an approved dose by a pediatric allergy and asthma specialist, at the rate of 0.5 cc per kilogram of the child's weight every 8 hours. Follow-up is done on the 3rd and 7th and 14th days by phone and according to the checklist .(The composition of the herbal drop,contains 10% of jujuba concentrate, 10% of chamomile concentrate and 80%

water as solvent)

Category

Treatment - Drugs

2

Description

Control group: 25 children with mild intermittent asthma will be included in the study if they meet the inclusion criteria and do not have the exclusion criteria. In addition to their standard treatment, patients receive placebo drops for up to 2 weeks, which are completely similar to the examined drug and prepared by a pharmacist, with a dose approved by a pediatric allergy and asthma specialist, at the rate of 0.5 cc per a kilogram of the child's weight every 8 hours. Follow-up is done on the 3rd and 7th and 14th days by phone and according to the checklis .(the Placebo drop composition includes 10% starch syrup)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Asthma and Allergy Clinic of Akbar Mashhad Hospital

Full name of responsible person

Dr.Hamid Ahanchian

Street address

Mashhad, Shahid Fakuri Boulevard, Shahid Javan Square, Shahid Kaveh Boulevard in front of Kaveh 14

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3871 3801

Fax

+98 51 3870 9201

Email

Ahanchianh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zojaj Darman Toos Pharmaceutical company

Full name of responsible person

Seyyed Abbas Zojaji

Street address

Technology Development Center,Mashhad University of Medical Sciences ,Bo Ali Square

City

Mashhad

Province
Razavi Khorasan

Postal code
9196773113

Phone
+98 51 3851 3590

Email
info@zojaj.club

Grant name

Grant code / Reference number

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

Title of funding source
Zojaj Darman Toos Pharmaceutical company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University of medical science mashhad branch

Full name of responsible person
Dr.Hamid Ahanchian

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Shahinfar Medical School , Emam Khomeini Ave.

City
Mashhad

Province
Razavi Khorasan

Postal code
9187147578

Phone
+98 51 3225 0041

Email
Ahanchianh@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zojaj Darman Toos Pharmaceutical Company

Full name of responsible person
Seyed Abbas Zojaji

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Bo Ali Square, Mashhad University of Medical Sciences Technology Development Center

City
Mashhad

Province
Razavi Khorasan

Postal code
9196773113

Phone
+98 51 3711 2611

Fax

Email
info@zojaj.club

Person responsible for updating data

Contact

Name of organization / entity
Zojaj Darman Toos Pharmaceutical Company

Full name of responsible person
Seyed Abbas Zojaji

Position
Proffesor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Bo Ali Square, Mashhad University of Medical Sciences Technology Development Center

City
Mashhad

Province
Razavi Khorasan

Postal code
9196773113

Phone
+98 51 3711 2611

Email
info@zojaj.club

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It is not yet known if there will be a plan to make this available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available