

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of sedative effect of thyme on cough in children 5 to 12 years of age with asthma

Protocol summary

Study aim

Evaluation of the sedative effect of thyme in cough in children with asthma

Design

In this double-blind clinical trial, phase 2, 60 children with asthma who have the inclusion criteria are placed in 2 parallel groups of 30 patients using a table of random numbers

Settings and conduct

In this study, 60 children with asthma aged 5 to 12 years who referred to the allergy clinic of Ardabil University of Medical Sciences were randomly divided into two groups (30 patients in each group). After obtaining written consent from the parents, general information and cough and fever, wheezing and other symptoms of respiratory infection will be collected. Patients in the intervention group will be given 1 to 4 grams of dried thyme leaf powder prepared as a syrup for a week, at a dose of 20 mg / kg every 8 hours along with routine medical treatment, and the control group will receive routine medical treatment and 2 cc placebo syrup .

Participants/Inclusion and exclusion criteria

Having asthma, age between 5-12 years, Lack of chronic disability or illness. Exclusion criteria: Failure to complete the course of treatment

Intervention groups

Intervention group: Patients in the intervention group will be given 1 to 4 grams of dried thyme leaf powder prepared as a syrup for a week, at a dose of 20 mg / kg every 8 hours, along prednisolone tablets (1 mg / kg, daily, Abureyhan Co.), salbutamol spray (2 puffs every 3 hours by Caspian Tamin Co), theophylline syrup (4 cc every 6 hours by Elixir Co) with routine medical treatment.. Control group: The control group will receive 2 cc placebo syrup and prednisolone tablets (1 mg / kg, daily, Abureyhan Co.), salbutamol spray (2 puffs every 3 hours by Caspian Tamin Co), theophylline syrup (4 cc every 6 hours by Elixir Co).

Main outcome variables

cough

General information

Reason for update

Incomplete number of patients

Acronym

IRCT registration information

IRCT registration number: **IRCT20200505047310N1**

Registration date: **2020-06-10, 1399/03/21**

Registration timing: **prospective**

Last update: **2021-03-11, 1399/12/21**

Update count: **2**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Elnaz Eskandarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3325 2251

Email address

e.eskandarpour@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of sedative effect of thyme on cough in children 5 to 12 years of age with asthma

Public title

Evaluation of the sedative effect of thyme in cough in children with asthma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having asthma age between 5-12 years Lack of chronic disability or illness

Exclusion criteria:

Failure to complete the course of treatment

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is a simple randomizing using a table of random numbers, a set of numbers which is completely generated randomly without any specific pattern or order in a table form. Table numbers are read from the left, in a way that even numbers are assigned to intervention A and odd numbers to intervention B. In this way, the researcher touches one of the numbers and moves to the right, then records the numbers and assigns them to different groups. Next, considering the volume of the research sample, aluminum wrapper envelopes are prepared (in order not to clarify the content of the envelopes), each of the random sequences is recorded on a card and placed inside an envelope. To maintain a random sequence, envelopes are numbered in the same way. Finally, the flap of the envelopes are sealed and respectively placed inside a box. To reveal the participants' assigned group, at the beginning of the registration based on the order of eligible participants entry to study, one of the envelopes is opened.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the fact that placebo is used, patients and outcome assessors are unaware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ardabil University of Medical Sciences

Street address

Daneshghah Street

City

Ardabil

Province

Ardabil

Postal code

561577664

Approval date

2019-08-10, 1398/05/19

Ethics committee reference number

1398.242.IR.ARUMS.REC

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

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

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

cough

Timepoint

Before and after the intervention

Method of measurement

Medical examination

Secondary outcomes**1****Description**

Fever

Timepoint

Before and after the intervention

Method of measurement

Thermometer

2

Description

wheezing

Timepoint

Before and after the intervention

Method of measurement

Medical Examination

Intervention groups

1

Description

Intervention group: Patients in the intervention group will be given 1 to 4 grams of dried thyme leaf powder prepared as a syrup for a week, at a dose of 20 mg / kg every 8 hours, along prednisolone tablets (1 mg / kg, daily, Abureyhan Co.), salbutamol spray (2 puffs every 3 hours by Caspian Tamin Co), theophylline syrup (4 cc every 6 hours by Elixir Co) with routine medical treatment.

Category

Treatment - Drugs

2

Description

Control group: Control group will receive 2 cc placebo syrup and prednisolone tablets (1 mg / kg, daily, Abureyhan Co.), salbutamol spray (2 puffs every 3 hours by Caspian Tamin Co), theophylline syrup (4 cc every 6 hours by Elixir Co) with routine medical treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Elnaz Eskandarpour

Street address

Moallem Street

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۳۶۴۳۱۹۷

Phone

+98 45 3325 2251

Email

e.eskandarpour@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Shahab Bohlooli

Street address

Daneshhah Street

City

Ardabil

Province

Ardabil

Postal code

5615783134

Phone

+98 45 3352 2247

Email

s.bohlooli@pharmacy.arums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Elnaz Eskandar pour

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Moallem Street

City

Ardabil

Province

Ardabil

Postal code

5615783134

Phone

+98 45 3325 2251

Email

e.eskandarpour@arums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Elnaz Eskandar pour

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Moallem Street

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۳۶۴۳۱۹۷

Phone

+98 45 3325 2251

Email

e.eskandarpour@arums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Elnaz Eskandar pour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Moallem Street

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۳۶۴۳۱۹۷

Phone

+98 45 3325 2251

Email

e.eskandarpour@arums.ac.ir

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable