Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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