

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation the effect of the " Prunus Dulcis Linctus" on asthmatic Patients (refractory with chronic cough)

Protocol summary

Study aim

Investigation of the effect of " Prunus Dulcis Linctus" on the Asthmatic Patients (refractory with Chronic Cough)

Design

A clinical trial with a control group, single_blind, non_random, phase 3 on 100 patients.

Settings and conduct

Patients selected from the breathing laboratory of Imam Reza hospital of Tabriz University of Medical Sciences, Iran in 2021. In this study, 100 Subjects were divided into two groups; one group was treated with Prunus Dulcis Linctus for 14 Days and another group took the only placebo (participants were not informed whether they receive the intervention drug or placebo).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age (>14) and chronic coughing. Patients with Kidney failure and Diabetes were excluded.

Intervention groups

Participants were divided into two groups (50 individuals in each); one group was treated with 15 g of the Prunus Dulcis Linctus (5 g in the morning , 5 g in the midday and 5 g at night) for 14 days and another group took the only placebo.

Main outcome variables

Intensity of chronic cough in the intervention and control groups.

General information

Reason for update

The company for supplying the Prunus Dulcis Linctus and placebo was changed from "Salamat Kodeh Baharan Traditional Medicine" company to "Andisheh Teb Boali" company.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210315050707N1**

Registration date: **2021-06-01, 1400/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-12, 1400/04/21**

Update count: **1**

Registration date

2021-06-01, 1400/03/11

Registrant information

Name

Maryam Seyyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 8093

Email address

maryamsiedy@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of the " Prunus Dulcis Linctus" on asthmatic Patients (refractory with chronic cough)

Public title

Investigation the effect of the " Prunus Dulcis Linctus" on treatment of cough

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with asthma whose cough has not been treated with common medications. Patients over 14 years
Patients who have signed the consent form.

Exclusion criteria:

Patients with Kidney failure and Diabetes Patients who were unavailable for follow-up

Age

From **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was conducted as a single_blind. Given that the appearance of the medicinal substance containing Prunus Dulcis Linctus extract is the same as that of Placebo medicinal substance, Patient werw not informed about the nature of them and they didn't know whether they were the main 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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Tuberculosis and Lung Diseases Research Center

City

Tabriz

Province

East Azarbaijan

Postal code

5142954481

Approval date

2021-05-17, 1400/02/27

Ethics committee reference number

IR.TBZMED.REC.1400.176

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Refractory Asthma

Timepoint

Comparison of Spirometry values as well as patient history before and two weeks after the "Prunus Dulcis Linctus" consumption.

Method of measurement

Spirometry test - Cough Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention group including fifty people, whose admission requirements has been confirmed according to determined criteria, was treated with 15 g of the Prunus Dulcis Linctus (5 g in the morning , 5 g in the midday and 5 g at night) for 14 days. Prunus Dulcis Linctus under study made by Andishe teb booli company,Iran .

Category

Treatment - Drugs

2

Description

Control group: including fifty people who their clinical features are the same as the intervention group. They received placebo instead of interventional as the same procedure as the intervention group. Placebo under study made by Andishe teb booli company, Iran .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital of Tabriz University of Medical Sciences, Iran

Full name of responsible person

Maryam Seyyedi

Street address

Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5142954481

Phone

+98 41 3337 8093

Fax

+98 41 3337 8093

Email

maryamsiedy@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Khalil Ansarin

Street addressTuberculosis and lung diseases research center,
Pashmineh street, Golgasht street.**City**

Tabriz

Province

East Azarbaijan

Postal code

5142954481

Phone

+98 41 3337 8093

Fax

+98 41 3337 8093

Email

Maryamsiedy@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Maryam Seyyedi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No.34, Nasiri str, Sahand.

City

Tabriz

Province

East Azarbaijan

Postal code

5331775666

Phone

+98 41 3361 9279

Fax

+98 41 3337 8093

Email

maryamsiedy@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Maryam Seyyedi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No.34, Nasiri str, Sahand.

City

Tabriz

Province

East Azarbaijan

Postal code

5331775666

Phone

+98 41 3361 9279

Fax

+98 41 3337 8093

Email

maryamsiedy@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Maryam Seyyedi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No.34, Nasiri str, Sahand.

City

Tabriz

Province

East Azarbaijan

Postal code

5331775666

Phone

+98 41 3361 9279

Fax

+98 41 3337 8093

Email

maryamsiedy@yahoo.com

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

There is not more Data for sharing.

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

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

Undecided - It is not yet known if there will be a plan to make this available