Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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) fot 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 Booali" 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)

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+98 41 3337 8093

Email address
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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 thay 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 booali 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 booali 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Tuberculosis and lung diseases research center, Pashmineh street, Golgasht street.
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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
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Researcher
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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