Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Propolis on clinical and physiological parameters of moderate Asthma. A double blind randomized placebo- controlled clinical trial.

Protocol summary

Summary

Introduction: Propolis has a long history of medicinal use, dating back to 250 B.C. This substance derived from honey and it is harmless. According to its inhibitory effect on IL2, IL6, IL1b, INFy and INF10 it potentially is able to improve asthma. It has also showed great anti_inflammatory effect because of its rich CAFÉ (caffeic acid phenethyl ester) content. Objectives: The propose of this study is to assess the effect of propolis on clinical findings and physiological parameters of asthma. Materials and methods: Inclusion criteria: Fifty subjects suffering from moderate asthma who have not received drugs for treatment of asthma will be enrolled in this double blind randomized placebo-controlled clinical trial. Subjects suffering from active infection, cigarette smoking and other respiratory diseases will be excluded from study. Primary outcome includes cough, score of ACT questionnaire, and FENO (Expiratory fraction of Nitric Oxide). Time point of outcome measurement is at the beginning of the study and at the end trial (3 weeks). The patients will be divided randomly into 2 groups whom one group will receive Propolis tablet and the other group will receive placebo for 3 weeks. A company will produce the Propolis and placebo in a similar shape. The physician and pharmacist will be blinded to the type of drug or placebo. Telephone call will use for home follow up. The study was approved by our local ethical committee and written inform consent will be given.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209302695N4**
Registration date: **2015-04-29, 1394/02/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-04-29, 1394/02/09

Registrant information

Name
Majid Mirsadraee
Name of organization / entity
Islamic Azad University- Mashhad branch
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Mashhad Branch, Islamic Azad University

Expected recruitment start date

2014-12-28, 1393/10/07

Expected recruitment end date

2015-12-19, 1394/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Propolis on clinical and physiological parameters of moderate Asthma. A double blind randomized placebo- controlled clinical trial.

Public title

Effect of Propolis on moderate asthma

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: New subjects suffering from cough or dyspnea with an intermittent course and history of airway hyper responsiveness; controller drugs was not started; spirometry of the patients showing moderate asthma (forced expiratory volume in the first second between 60 to 80%). Exclusion criteria: mild (FEV1 mare than 80%); severe asthma (FEV1<60%); respiratory infection; treatment with systemic corticosteroid; rhinosinusitis; gastroesophageal reflux disease; other obstructive lung disease; Churg–Strauss syndrome; smokers; vocal cord dysfunction; reactive airway dysfunction syndrome.

Age
From **7 years** old to **90 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
All recruited asthmatic subjects will randomly divided into two groups (Propolis and placebo) by computer generated randomization list. The physician and pharmacist are blind to the exact drug. Propolis and placebo will be packed in bottle with similar appearance and they will get code according to the randomization schedule.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committee of Medical school Islamic Azad University- Mashhad branch

Street address
Shahin Far Building , Azadi street , sarab alley

City
mashhad

Postal code
۹۱۷۸۶۷۳۷۹۹

Approval date
2012-04-26, 1391/02/07

Ethics committee reference number
A34-18

Health conditions studied

1

Description of health condition studied
asthma

ICD-10 code
j459

ICD-10 code description
asthma , unspecified

Primary outcomes

1

Description
Fractional exhaled Nitric Oxide (FENO)

Timepoint
at the beginning of the study and at the end of the three weeks treatment

Method of measurement
expiratory nitric oxide test with NObreath equipment

2

Description
ACT score test

Timepoint
At the beginning of the study and at the end of the three weeks treatment

Method of measurement
ACT questionnaire

Secondary outcomes

1

Description
Interleukin -4 (IL-4)

Timepoint
At the begining and at the end of the three weeks of therapy

Method of measurement
ELIZA

2

Description
Interleukin-17 (IL-17)

Timepoint
At the begining and at the end of the three weeks of therapy

Method of measurement
ELIZA

3

Description
Interferon-Y (INF-Y)

Timepoint

At the begining and at the end of the three weeks of therapy

Method of measurement

ELIZA

4

Description

Toll Like Receptor-2 (TLR-2)

Timepoint

At the begining and at the end of the three weeks of therapy

Method of measurement

ELIZA

5

Description

Dyspnea

Timepoint

At the beginning of the study and at the end of the three weeks treatment

Method of measurement

MMRC questionnaire

6

Description

Forced expiratory volume in one second

Timepoint

at the beginning of the study and at the end of the three weeks treatment

Method of measurement

spirometry

7

Description

inflammatory cells of sputum

Timepoint

At the beginning of the study and at the end of the three weeks treatment

Method of measurement

sputum cytology

8

Description

Cough

Timepoint

Before and after three weeks of trial time point

Method of measurement

Clinical assessment

Intervention groups

1

Description

Moderate stage asthmatic subjects whom were not previously treated will be evaluated for clinical findings, spirometry, asthma control test, FENO, sputum cytology, IL-4 ، IFN-γ ، IL-17 and TLR-2 at the onset of the study. The subjects will be randomly divided in to two groups. Package of propolis and placebo will be produced in similar appearance and case group will recieve a pack ot Propolis which each pack contains 21 pills and each pill contains 125 mg. The package will get coded base on the random number table by a third person whom will be blind to groups. The code will be saved when the drug gives to the patient. The physician and pharmacist will blind to the codes. The subjects will follow during three weeks period of treatment by telephone call for assessing the side effects and exacerbation of symptoms. Emergency usage of Salbutamol inhaler will be permitted as needed. After 3 weeks the mentioned assessment will be repeated.

Category

Treatment - Drugs

2

Description

Control group: Moderate stage asthmatic subjects who randomly allocated in control group will be evaluated for clinical findings, spirometry, asthma control test, FENO, sputum cytology, IL-4 ، IFN-γ ، IL-17 and TLR-2 as the same as trial group. Package of propolis and placebo will produce in similar appearance and in this group the pack contains 21 placebo pills. The package will get coded base on the random number table by a third person who will be blind to groups. The physician and pharmacist will keep blind to the codes. The subjects will follow during three weeks period of treatment by telephone call for assessing the side effects and exacerbation of symptoms. Emergency usage of Salbutamol inhaler will be permitted as needed. After 3 weeks the mentioned assessment will be repeated.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Mashhad Branch

Full name of responsible person

Mojtaba Mashkat

Street address

Shahin-far building, Azadi street, Sarab alley

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University of Mashhad

Full name of responsible person

Mojtaba Meshkat

Street address

Shahin-far building, Azadi street, Sarab alley

City

MAshhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University of Mashhad

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Majid Mirsadraee

Position

Associate professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty