

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of squill oxymel, Traditional Medicine product, in the treatment of moderate to severe asthma in patients 18 to 70 years old: triple-blind randomized Clinical trial

Protocol summary

Summary

The purpose of this study is to evaluate the effect of Squill Oxymel in the patients with asthma. The study is a randomized, triple-blind and single-center which will be carried out on 51 patients with moderate to severe asthma referred to Imam Khomeini Hospital. Inclusion criteria include: age 18 to 50 years, treated with conventional medications and patients with moderate to severe asthma that was insufficiently controlled despite treatment with medium or high dose inhaled corticosteroids. Exclusion criteria include: add or remove the drugs that interfere with asthma (NSAIDs and corticosteroids) and infections leading to hospitalization. Method: with randomization (blocks), Patients will be divided into 3 groups of 17 people: Intervention Group 1 (Squill Oxymel, Oral Syrup, 10 ml twice a day), Intervention Group 2 (simple Honey Oxymel, Oral Syrup, 10 ml twice a day) and Control Group (placebo). Patients will be treated for 6 weeks. The Primary outcomes included quality of life and FEV1. Secondary outcomes included the FEV1 / FVC, RV, TLC, RV / TLC and RAW. These changes will be assessed with the quality of life questionnaires St. George (SGRQ), spirometry breathing test and wind box before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111119912N1**
Registration date: **2015-02-12, 1393/11/23**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-02-12, 1393/11/23

Registrant information

Name

Hossein Karegar-Borzi

Name of organization / entity

College of Traditional Medicine of Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-02-14, 1393/11/25

Expected recruitment end date

2015-06-15, 1394/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of squill oxymel, Traditional Medicine product, in the treatment of moderate to severe asthma in patients 18 to 70 years old: triple-blind randomized Clinical trial

Public title

Evaluation of the effect of squill oxymel In asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 70 years; asthma patients with moderate to severe asthma who have clinical criteria include: FEV1 between 40% to 80% of the predicted and asthma that was insufficiently controlled despite treatment with medium or high dose inhaled corticosteroids; treated with conventional drugs; Lack of pregnancy; Lack of breastfeeding; Lack of the use other herbal medicines; Lack of active peptic ulcer and cardiovascular disease (especially heart block) or renal disease; Not concomitant use of anticoagulant; Non-smoking. Exclusion criteria: Add or remove the drugs that interferes with asthma (such as NSAIDs); Infections leading to hospitalization; the patient's unwillingness to continue treatment.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, Keshavarz Ave., Tehran

City

Tehran

Postal code**Approval date**

2014-11-09, 1393/08/18

Ethics committee reference number

9021309004-126326

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

Asthma

ICD-10 code

J45

ICD-10 code description

asthma

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

asthma quality of life

Timepoint

Before and after the intervention (end of week 6)

Method of measurement

St. George's Respiratory Questionnaire (SGRQ)

2**Description**

FEV1

Timepoint

Before and after the intervention (end of week 6)

Method of measurement

Spirometry testing

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

FEV1/FVC

Timepoint

Before and after the intervention (end of week 6)

Method of measurement

Spirometry testing

2**Description**

RV (Residual Volume)

Timepoint

Before and after the intervention (end of week 6)

Method of measurement

body box plethysmography

3**Description**

TLC (total lung capacity)

Timepoint

Before and after the intervention (end of week 6)

Method of measurement

body box plethysmography

4**Description**

RV/TLC

Timepoint

Before and after the intervention (end of week 6)
Method of measurement
body box plethysmography

5

Description
RAW total (Resistance Air Way total)
Timepoint
Before and after the intervention (end of week 6)
Method of measurement
body box plethysmography

6

Description
RAW in, ex (Resistance Air Way)
Timepoint
Before and after the intervention (end of week 6)
Method of measurement
body box plethysmography

Intervention groups

1

Description
Intervention Group1 (Medication): Squill Oxymel (traditional medicine products) Oral Syrup (250ml), 10 ml twice a day for 6 weeks
Category
Treatment - Drugs

2

Description
Intervention Group2 (Medication): simple Honey Oxymel Oral Syrup (250ml), 10 ml twice a day for 6 weeks
Category
Treatment - Drugs

3

Description
Control Group (placebo): a mixture of honey, water, color additive, etc. Oral Syrup (250ml), 10 ml twice a day for 6 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mehrnaz Asadi
Street address
Keshavarz Blvd., Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
College of Traditional Medicine of Tehran University of Medical Sciences
Full name of responsible person
Dr. Roja Rahimi
Street address
College of Traditional Medicine of Tehran University of Medical, Behesht Street, Vahdat Eslami Street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
College of Traditional Medicine of Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Hossein Karegar-Borzi
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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