

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation the effect of squill oxymel, Traditional Medicine product, in the treatment of chronic obstructive pulmonary disease (COPD) in patients 18 to 60 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 chronic obstructive pulmonary disease (COPD). The study is a randomized, triple-blind and single-center which will be carried out on 42 patients with stage IIA COPD referred to Imam Khomeini Hospital. Inclusion criteria include: Age 18 to 60 years, patients with GOLD stage IIA COPD who have clinical criteria include: FEV1/FVC less than 0.7 of the predicted and FEV1 between 50% to 80% of the predicted and treated with conventional drugs. Exclusion criteria: Add or remove the drugs that interferes with COPD (such as NSAIDs) and Infections leading to hospitalization. Method: with randomization (blocks), Patients will be divided into 2 groups of 21 people: Intervention Group (Squill Oxymel, Oral Syrup, 10 ml twice a day) and Control Group (placebo, Oral Syrup, 10 ml twice a day). Patients will be treated for 6 weeks. The Primary outcome is the distance traveled in the 6MWT. Secondary outcomes include quality of life and Blood oxygen saturation (SaO₂). These changes will be assessed with the quality of life questionnaires St. George (SGRQ) and the 6-minute walk test (6MWT) before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040919912N2**
Registration date: **2016-09-22, 1395/07/01**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-22, 1395/07/01

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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Phone

+98 21 2298 8550

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Recruitment status

Recruitment complete

Funding source

College of Traditional Medicine of Tehran University of Medical Sciences

Expected recruitment start date

2016-10-16, 1395/07/25

Expected recruitment end date

2017-04-14, 1396/01/25

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 chronic obstructive pulmonary disease (COPD) in patients 18 to 60 years old: triple-blind randomized Clinical trial

Public title

Evaluation of the effect of squill oxymel In COPD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 60 years; patients with GOLD stage IIA COPD who have clinical criteria include: FEV1/FVC less than 0.7 of the predicted and FEV1 between 50% to 80% of the predicted; 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 COPD (such as NSAIDs); Infections leading to hospitalization; the patient's unwillingness to continue treatment.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

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

2015-11-03, 1394/08/12

Ethics committee reference number

IR.TUMS.REC.1394.1092

Health conditions studied

1

Description of health condition studied

chronic obstructive pulmonary disease (COPD)

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

distance traveled in the 6MWT

Timepoint

Before and after the intervention (end of week 6)

Method of measurement

6-minute walk test (6MWT)

Secondary outcomes

1

Description

quality of life

Timepoint

before and after the intervention (6 week)

Method of measurement

quality of life questionnaires St. George (SGRQ)

2

Description

Blood oxygen saturation (SaO2)

Timepoint

before and after the intervention (6 week)

Method of measurement

6-minute walk test (6MWT)

Intervention groups

1

Description

Intervention Group (Medication): Squill Oxymel (traditional medicine products) Oral Syrup (250ml), 10 ml twice a day for 6 weeks

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Roja Rahimi

Street address

Department of Traditional Pharmacy, School of
Traditional Medicine, Tehran University of Medical
Sciences, Enghelab Square, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Position

PhD Student of Traditional Medicine

Other areas of specialty/work

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Web page address

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