Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Iran (Islamic Republic of)
Phone
+98 21 2298 8550
Email address
h-karegar@razi.tums.ac.ir

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
Street address
Faculty of Traditional Medicine, Tehran University of Medical Sciences, Jamali St., Heravi Square, Tehran
City
Tehran
Postal code
Phone
+98 21 2298 8550
Fax
Email
h-karegar@razi.tums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Faculty of Traditional Medicine, Tehran University of Medical Sciences, Jamali St., Heravi Square, Tehran
City
Tehran
Postal code
Phone
+98 21 2298 8550
Fax
Email
h-karegar@razi.tums.ac.ir
Web page address

Person responsible for updating data

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
Street address
Faculty of Traditional Medicine, Tehran University of Medical Sciences, Jamali St., Heravi Square, Tehran
City
Tehran
Postal code
Phone
+98 21 2298 8550
Fax
Email
h-karegar@razi.tums.ac.ir
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