Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of the the Squill-Oxymel on patients with occupational obstructive pulmonary disease: A Pilot Randomized Triple-Blinded Placebo-Controlled Clinical Trial

Protocol summary

Study aim

To evaluate the effects of Squill Oxymel on pulmonary function, respiratory symptoms, and treatment tolerability in patients with occupational obstructive lung diseases compared with placebo

Design

A randomized, placebo controlled clinical trial with a two by two factorial design, individual block randomization, and planned blinding of participants, investigators, and outcome assessors. A total of 144 participants will be equally allocated to four groups of 36

Settings and conduct

The study will be conducted in Semnan, Iran, among workers with occupational obstructive lung diseases. Eligible participants will receive the assigned intervention for 60 days. Pulmonary function and respiratory symptoms will be assessed at baseline, day 30, and day 60. Coded study products will maintain blinding to active treatment or placebo

Participants/Inclusion and exclusion criteria

Workers aged 18 to 65 years with at least one year of occupational exposure to respiratory hazards, chronic respiratory symptoms, and spirometric evidence of airflow obstruction will be included. Exclusion criteria include nonobstructive pulmonary diseases, severe cardiovascular diseases, smoking history exceeding 20 pack years, recent respiratory infections, pregnancy, and breastfeeding

Intervention groups

Group A receives Squill Oxymel plus standard treatment; Group B receives placebo plus standard treatment; Group C receives Squill Oxymel without standard treatment; Group D receives placebo without standard treatment. The intervention duration is 60 days

Main outcome variables

Changes in forced expiratory volume in one second (FEV1); forced vital capacity (FVC); FEV1/FVC ratio; forced expiratory flow between 25% and 75% of FVC (FEF25–75); peak inspiratory flow (PIF)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170704034900N4**
Registration date: **2026-10-22, 1405/07/30**
Registration timing: **prospective**

Last update: **2026-10-22, 1405/07/30**
Update count: **0**

Registration date

2026-10-22, 1405/07/30

Registrant information

Name
Daryoush pahlevan
Name of organization / entity
Semnan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 23 3365 4162
Email address
dpahlevan@semums.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-21, 1405/08/30

Expected recruitment end date

2027-01-20, 1405/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effect of the the Squill-Oxymel on patients with occupational obstructive pulmonary disease: A Pilot Randomized Triple-Blinded Placebo-Controlled Clinical Trial

Public title
Studying the effect of the the Squill-Oxymel on patients with occupational obstructive pulmonary disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years Employment in an occupational environment with documented exposure to respiratory hazards for at least one year Documented occupational exposure to respiratory hazards such as industrial dust, fumes, chemical vapors, or gases Presence of chronic respiratory symptoms consistent with obstructive lung disease, including dyspnea, chronic cough, wheezing, or chest tightness Spirometric findings consistent with obstructive lung disease, including reduced FEV1 and an FEV1/FVC ratio below 0.70 Ability to perform acceptable and reproducible spirometry according to ATS/ERS standards
Exclusion criteria:
Presence of non-obstructive pulmonary diseases History of severe cardiovascular diseases History of heavy smoking exceeding 20 pack-years Active respiratory infection or history of respiratory infection within the past four weeks Pregnancy or breastfeeding Unwillingness to participate in the study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, individual-level block randomization will be used to allocate eligible participants to the study groups. After assessment of the inclusion and exclusion criteria and obtaining written informed consent, participants will be randomly assigned in a 1:1:1:1 allocation ratio to four groups: Group A (Squill-Oxymel plus standard treatment), Group B (placebo plus standard treatment), Group C (Squill-Oxymel without standard treatment), and Group D (placebo without standard treatment). It is proposed that the random allocation sequence be generated using statistical software with randomly varying block sizes of 4 and 8 by an independent researcher who is not involved in participant recruitment, clinical assessment, or outcome evaluation. Within each block, participants will be randomly allocated to the four study groups to maintain balanced group sizes while minimizing the predictability of subsequent assignments. No stratification is proposed. To ensure allocation concealment, it is proposed that the randomization sequence be maintained by an independent researcher using sequentially numbered, opaque, sealed envelopes. Each envelope will be opened only after confirmation of eligibility, completion of baseline assessments, and formal enrollment of the participant. Allocation codes will remain confidential until completion of the study and data analysis, except when emergency unblinding is necessary to ensure participant safety.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, blinding will be implemented to minimize potential bias during intervention administration and outcome assessment. Three categories, including participants, the investigator, and outcome assessors, will be blinded to the allocation of Squill-Oxymel or placebo. Squill-Oxymel syrup and placebo will be prepared to be as similar as possible in color, taste, odor, consistency, volume, and packaging. The study products will be labeled with unique identification codes without indicating whether they contain the active intervention or placebo. Product coding will be performed by an independent individual who is not involved in the research procedures. The confidential code list will be securely maintained until completion of the study. Participants will be informed about their participation in the clinical trial and the possibility of receiving either Squill-Oxymel or placebo, but they will remain unaware of the assigned product. The investigator responsible for conducting the study and the outcome assessors will not have access to the treatment allocation codes. Pulmonary function outcomes, including FEV1, FVC, FEV1/FVC, FEF25–75, and PIF, will be assessed at baseline, day 30, and day 60 without the outcome assessors being informed of the assigned study product. Clinical care providers responsible for prescribing or supervising standard treatment may not be blinded to the standard-treatment component of group allocation if they are aware of whether participants receive standard treatment. Adverse events and clinical conditions will be monitored and documented throughout the study. Emergency unblinding will be permitted when knowledge of the assigned study product is essential for appropriate clinical management of a serious adverse event.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Deputy of Research and Technology, Central Headquarters, Semnan University of Medical Sciences, Basij Boulevard, Semnan, Iran

City
semnan

Province
Semnan

Postal code
3514799442

Approval date
2026-07-27, 1405/05/05

Ethics committee reference number
IR.SEMUMS.REC.1405.085

Health conditions studied

1

Description of health condition studied
occupational asthma

ICD-10 code
J45.9

ICD-10 code description
Other and unspecified asthma

2

Description of health condition studied
Occupational Chronic Obstructive Pulmonary Disease (Occupational COPD)

ICD-10 code
J44.9

ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
Change in forced expiratory volume in one second from baseline following the intervention

Timepoint
At baseline before the intervention and on days 30 and 60 after initiation of the intervention

Method of measurement
Measurement using a calibrated spirometer according to the American Thoracic Society and European Respiratory Society standards, expressed in liters

Secondary outcomes

1

Description
Change in forced vital capacity from baseline following the intervention

Timepoint
At baseline before the intervention and on days 30 and 60 after initiation of the intervention

Method of measurement
Measurement using a calibrated spirometer according to the American Thoracic Society and European Respiratory Society standards, expressed in liters

Intervention groups

1

Description
Intervention group: Intervention group 1: Participants in this group will receive Squill Oxymel syrup manufactured by Niak Pharmaceutical Company, a traditional herbal formulation containing squill (Drimia maritima), honey, and vinegar, supplied in 200 mL bottles. The syrup will be administered orally at a dose of 10 mL twice daily for 60 days. Participants will continue to receive standard treatment for occupational obstructive lung disease as prescribed by their treating physician.

Category
Treatment - Drugs

2

Description
Intervention group: Intervention group 2: Participants in this group will receive Squill Oxymel syrup manufactured by Niak Pharmaceutical Company, a traditional herbal formulation containing squill (Drimia maritima), honey, and vinegar, supplied in 200 mL bottles. The syrup will be administered orally at a dose of 10 mL twice daily for 60 days. According to the initial study protocol, participants in this group will not receive standard treatment for occupational obstructive lung disease.

Category
Treatment - Drugs

3

Description
Control group: Control group: Participants in this group will receive 10 mL of oral placebo syrup twice daily for 60 days. The placebo will be prepared to match the Squill Oxymel syrup manufactured by Niak Pharmaceutical Company in color, taste, odor, consistency, volume, and packaging, but will not contain the active constituents of the squill plant. Participants will continue to receive standard treatment for occupational obstructive lung disease as prescribed by their treating physician.

Category
Placebo

4

Description
Control group: Intervention group 3: Participants in this group will receive 10 mL of oral placebo syrup twice daily for 60 days. The placebo will be prepared to match the active Squill Oxymel formulation in appearance and packaging, without containing the active constituents of the squill plant. According to the initial study protocol, participants in this group will not receive standard treatment for occupational obstructive lung disease.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
kosar hospital
Full name of responsible person
daryosh pahlevan
Street address
jahad bridge
City
semnan
Province
Semnan
Postal code
3519899558
Phone
+98 23 3142 0000
Email
kosarhos@semums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Majid eslami
Street address
Deputy of Research and Technology, Central Headquarters, Semnan University of Medical Sciences, Basij Boulevard, Semnan, Iran
City
semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
sem.ums.res@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan University of Medical Sciences
Proportion provided by this source
10
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

2

Sponsor
Name of organization / entity
Niak pharmaceutical company
Full name of responsible person
Dr. Houman Bayat
Street address
11th kilometer Gorgan-Aqqalla road
City
Gorgan
Province
Golestan
Postal code
۴۹۳۱۱۵۳۱۴۱
Phone
+98 17 3451 6192
Email
niak.pharmaceutical@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Niak pharmaceutical company
Proportion provided by this source
90
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
sobhan sangesari
Position

دانشجو
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Imam Town, next to Maskan-e Melli
City
sorkheh
Province
Semnan
Postal code
3551763457
Phone
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Email
sobhansangesari@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Daryosh Pahlevan
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Occupational Medicine
Street address
Headquarters, Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan, Iran
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3344 1022
Email
dpahlevan@semums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
sobhan sangesari
Position
دانشجو
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Imam Town, next to Maskan-e Melli
City
sorkheh
Province
Semnan
Postal code
3551763457
Phone
+98 23 3361 5232
Email
sobhansangesari@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Deidentified individual participant data collected during the clinical trial, including demographic characteristics, pulmonary function measurements, respiratory symptoms, treatment allocation, and adverse events, as well as the study protocol and data collection forms. All personal identifiers will be removed before sharing.
When the data will become available and for how long
Data and supporting documents will be available beginning six months after publication of the main study results and will remain accessible for five years thereafter, subject to applicable ethical and institutional requirements.
To whom data/document is available
Qualified researchers affiliated with universities, academic institutions, research centers, or healthcare organizations may request access to the data and supporting documents for legitimate scientific purposes.
Under which criteria data/document could be used
Data may be used for scientific research, secondary analyses, systematic reviews, and meta analyses. Applicants must submit a research proposal describing the intended use of the data. Access will be subject to approval by the principal investigator and applicable ethics requirements. Attempts to identify participants, unauthorized redistribution, and commercial use without permission are prohibited.
From where data/document is obtainable
Data access requests should be submitted by email to the research team at Semnan University of Medical Sciences, Semnan, Iran. Contact person: Sobhan Sangesari Email: sobhansangesari@gmail.com Requests will be forwarded to the principal investigator for review and approval.
What processes are involved for a request to access

data/document

Applicants must submit a written request specifying their institutional affiliation, research objectives, and intended analyses. The research team will review the request and assess ethical compliance. A decision will normally be communicated within 30 days of receiving a complete application. Following approval and completion of any required data sharing agreement, the requested documents or deidentified data will be provided through a secure electronic method within 15 working days.

Comments