

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the effects of propolis- echinacea supplementation on Chronic fatigue syndrome and quality of life in lung cancer patients (NSCLC) consuming Pemetrexed

Protocol summary

Study aim

Evaluation of the effects of propolis-echinacea supplementation on chronic fatigue syndrome and quality of life in lung cancer patients (NSCLC) consuming pemetrexed

Design

Clinical trial, single group, phase 3 on 40 patients, enrolled from patients who refer to Masih Daneshvari Hospital with a diagnosis of NSCLC and are candidates to receive pemetrexed for the first time.

Settings and conduct

This clinical trial and prospective study of before-after will take place in the Masih Daneshvari Hospital. Forty patients diagnosed with NSCLC by an oncologist according to NCCN protocols. These patients are candidates to receive pemetrexed. Fatigue and quality of life in the patients will be assessed with EQ-5F-3L and BFI questionnaires. Finally, the effects of intervention will be evaluated following completing the questionnaires and analyzing data by SPSS software and statistical analyses.

Participants/Inclusion and exclusion criteria

The inclusion criteria include patients who refer to Masih Daneshvari hospital with a diagnosis of NSCLC and are candidates for receiving pemetrexed for the first time. Exclusion criteria also include patients who are allergic to drugs, suffering from underlying nerve disorders, patients addicted to drugs, patients using hypnotics and neuroleptics, patients with Hypothyroidism and patients who need surgery and are pregnant and lactating.

Intervention groups

Propolis- echinacea supplement tablet of 450 mg twice daily for one month patients with lung cancer patients (NSCLC) consuming pemetrexed.

Main outcome variables

Fatigue status and quality of life in non-small cell lung cancer (NSCLC) patients using Pemetrexed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N33**

Registration date: **2023-05-20, 1402/02/30**

Registration timing: **prospective**

Last update: **2023-05-20, 1402/02/30**

Update count: **0**

Registration date

2023-05-20, 1402/02/30

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty		Province	Tehran
Scientific title		Postal code	1991953381
Evaluation of the effects of propolis- echinacea supplementation on Chronic fatigue syndrome and quality of life in lung cancer patients (NSCLC) consuming Pemetrexed		Approval date	2023-01-10, 1401/10/20
Public title		Ethics committee reference number	IR.SBMU.PHARMACY.REC.1401.220
Evaluation of the effects of propolis- echinacea supplementation on Chronic fatigue syndrome and quality of life in lung cancer patients (NSCLC) consuming Pemetrexed		Health conditions studied	
Purpose		<u>1</u>	
Prevention		Description of health condition studied	
Inclusion/Exclusion criteria		Non-small cell lung cancer (NSCLC)	
Inclusion criteria:		ICD-10 code	
Lung cancer patients (NSCLC) consuming Pemetrexed		C34.9	
Exclusion criteria:		ICD-10 code description	
Patients who are allergic to medicine Patients with hypothyroidism Patients using hypnotics and neuroleptics Patients addicted to drugs Suffering from underlying nerve disorders Patients who need surgery Pregnant and lactating		Malignant neoplasm of unspecified part of bronchus or lung	
Age		Primary outcomes	
From 18 years old		<u>1</u>	
Gender		Description	
Both		Quality of life score based on EQ-5D-3L questionnaire	
Phase		Timepoint	
3		Measuring the quality of life based on the EQ-5D-3L questionnaire on days 0 and 28	
Groups that have been masked		Method of measurement	
No information		EQ-5D-3L questionnaire	
Sample size		<u>2</u>	
Target sample size: 40		Description	
Randomization (investigator's opinion)		Fatigue complication score based on BFI questionnaire	
Not randomized		Timepoint	
Randomization description		Measurement of fatigue complication score based on BFI questionnaire on days 0-7-14-21-28	
Blinding (investigator's opinion)		Method of measurement	
Not blinded		BFI questionnaire	
Blinding description		Secondary outcomes	
Placebo		<u>1</u>	
Not used		Description	
Assignment		Hospitalization rate	
Single		Timepoint	
Other design features		Before intervention and one month after the end of intervention	
Secondary Ids		Method of measurement	
empty		Patient's record	
Ethics committees		<u>2</u>	
<u>1</u>		Description	
Ethics committee		Rate of infection	
Name of ethics committee		Timepoint	
Ethics Committee in Research of Pharmacy, Nursing and Midwifery Faculties - Shahid Beheshti Universi		Before intervention and one month after the end of intervention	
Street address			
No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran			
City			
Tehran			

Method of measurement

Patient's record

Intervention groups

1

Description

Intervention group: Novohil drug manufactured by Faran Chemical Factory with a dose of 450 mg (containing 400 mg of propolis and 50 mg of echinacea) is administered orally to patients twice a day for one month.

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Masih Daneshvari Hospital

Full name of responsible person

Farzaneh dastan

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

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Tehran

Province

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1956944413

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Web page address

<https://nritld.sbmu.ac.ir/index.jsp?fkeyid=&siteid=200&pageid=32488>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farzaneh Dastan

Street address

3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

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Province

Tehran

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1983963113

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mpd@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirreza rahimi

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Shahid Beheshti Faculty of Pharmacy, Niayesh Highway, Valiasr Ave, Tehran, Iran

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Rahimi.amir2000@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farzaneh dastan

Position

Assistant Professor, Clinical Pharmacy Specialist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Email

Rahimi.amir2000@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the potential data can be shared after blinding.

When the data will become available and for how long

Researchers working in academic institutions

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and meta-analysis studies

From where data/document is obtainable

Dr. Farzaneh Dastan, Dr. Masih Daneshvari Hospital,
Daar-Abad, Niavaran

What processes are involved for a request to access data/document

Official letter to the researchers through Email
(fzh.dastan@gmail.com)

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirreza rahimi

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

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City

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