

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of ginseng on cancer related fatigue and Quality of life in cancer survivors: a randomized controlled clinical trial study

Protocol summary

Summary

Fatigue is one of the most common problems in cancer patients. This problem can affect the quality of life of these people. By choosing the appropriate method, patients' problems can be cured and patients' quality of life can be increased. Among different methods, the use of herbal medicines has been considered by many researchers. One of the famous medicinal herbs mentioned in various articles is ginseng. The aim of this study was to investigate the effect of ginseng on fatigue and quality of life in cancer patients. This study is a double-blind, randomized, controlled clinical trial. Study population: Cancer survivors referring to Shahid Ghazi Tabriz center and the time of study in 2017-2018. The inclusion criteria included diagnosed cancer (colorectal, stomach) According to the oncologist, the patient's consciousness, lack of mental and brain illness in the patient's medical history indicated. Fatigue score above 4 (maximum score 10), aged 65-18 years, patients at stage II and I of the disease. Exclusion criteria: a disturbing sleep medications such as diuretic drugs, antidepressants, and amphetamine inotrope at night, have a history of blood pressure in patients taking anticoagulant drugs (aspirin and heparin), Diabetes. Study tools: Brief Fatigue Inventory (BFI) and the standard quality of life-related cancer tool (EORTC QLQ-C30 (version 3)). Method of intervention: Participants will be randomly assigned to the intervention and control groups using a four-way blocking method. The study is double-blind. patients and researchers are unaware of what medicine and placebo are. Boxes will be encoded by someone who is not involved in the sampling. The intervention group received 250 mg daily ginseng capsules, and was given to the placebo control group. Pre-test samples are taken before intervention begins. The medication / placebo will be for 28 days. 28 days after the intervention, the post-test will be taken. Then, by using SPSS V.14 software, descriptive and analytical tests will examine the study objectives.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101536777N1**
Registration date: **2017-10-25, 1396/08/03**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-25, 1396/08/03

Registrant information

Name

Musab Ghaderi

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 937 809 5753

Email address

musab.ghaderi@tbzmedn.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences

Expected recruitment start date

2017-11-06, 1396/08/15

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ginseng on cancer related fatigue and Quality of life in cancer survivors: a randomized controlled clinical trial study

Public title

The effect of ginseng on cancer related fatigue and Quality of life in cancer survivors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: A definitive diagnosis of cancer according to the opinion of the oncologist Fatigue score above 4 (out of 10) Aged 65-18 years Patients in stage II, I disease. Patients with colorectal , stomach cancer Not having hypertension Not having diabetes Exclusion criteria: Get the anesthetic and narcotic drugs during the study The patient's unwillingness to continue participating in the study Occurrence of acute problems during the study The existence of mental and brain illness in the patient's medical history indicated. Receiving sleep disturbances such as diuretics, antidepressants, inotropes and amphetamines at night Need for cardiopulmonary resuscitation during intervention Pregnant and lactating women Receive oral antidiabetic medicines Coagulation therapy (aspirin, heparin) Having a history of seizure

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz university of medical science

Street address

East Azerbaijan Province, Tabriz, Univesity Main St

City

Tabriz

Postal code**Approval date**

2017-07-23, 1396/05/01

Ethics committee reference number

iR.TBZMED.REC.1396.345

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

Cancer

ICD-10 code

c80.9

ICD-10 code description

c80.9

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

fatigue

Timepoint

before intervention, once month after intervention

Method of measurement

Brief Fatigue Inventory (BFI)

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

quality of life

Timepoint

before intervention, once month after intervention

Method of measurement

EORTC QLQ-C30 (version 3)

Intervention groups**1****Description**

In this study, standardized ginseng extract was given to patients in 250 mg capsules daily for four weeks. In order to hide the drug with placebo in similar envelopes, they will be put in matte pack. Assignment and sequencing of allocation and preparation of packets containing ginseng with placebo will be done by a person not involved in the sampling and analysis of the data by numbering on sub-boxes.

Category

Treatment - Drugs

2**Description**

In this study, Placebo capsules same as the original

medicine, patients are given daily for four weeks. In order to hide the drug with placebo in similar envelopes, they will be put in matte pack. The assignment and sequencing of the envelopes containing Jensen with Placeco by a non-person involved in the sampling and analysis of the data will be done by numbering the sub-boxes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghazi Tabatabaee Hospital Tabriz

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences, Tabriz Faculty of Nursing and Midwifery

Full name of responsible person

Musab.ghaderi

Street address

South Shariati St., Faculty of Nursing and Midwifery, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences, Tabriz Faculty of Nursing and Midwifery

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

Tabriz University of Medical Sciences, Tabriz Faculty

of Nursing and Midwifery

Full name of responsible person

Musab ghaderi

Position

student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Associate Professor

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

student

Other areas of specialty/work

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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