

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Assessment of ginger and corn starch effect on chemotherapy-induced neuropathy in patients with ovarian and lung cancer

Protocol summary

Summary

Neuropathy is the major dose-limiting side effect of chemotherapeutic agents of paclitaxel and carboplatin. Ginger has anti-inflammatory, anti-oxidative and neuroprotective properties. The aim of this study is evaluating the prophylactic effect of ginger against chemotherapy-induced peripheral neuropathy. Inclusion criteria consist of suffering from ovarian or non-small cell lung cancer. Patients with history of other malignancies or degenerative neurological disorders will be excluded from the study. Accordingly, 52 patients will be enrolled in this study and they will be allocated randomly into supplemented group with 2 g daily ginger or corn starch placebo (2 one-gram tablets) during chemotherapy period for 18 weeks. Incidence and severity of CIPN will be assessed before the onset of and at the end of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121415780N1**

Registration date: **2014-03-15, 1392/12/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-15, 1392/12/24

Registrant information

Name

Zohreh Ghoreishi

Name of organization / entity

Nutrition Research Center, Tabriz University of
Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Applied Drug Research Center, Nutrition Research Center, Physical Medicine & Rehabilitation Research Center, Hematology and Oncology Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2015-07-11, 1394/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of ginger and corn starch effect on chemotherapy-induced neuropathy in patients with ovarian and lung cancer

Public title

Ginger effect on chemotherapy-induced neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria:suffering from ovarian cancer; non-small cell lung cancer; willingness to cooperate. Exclusion Criteria:age more than 70 years; suffering from diabetes; AIDS;hyperthyroidism; primary neurological diseases; other kinds of malignancies; history of chemotherapy; consumption of vitamin; mineral or fish oil supplementation at list 3 months before the enrollment;

Ginger sensitivity

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **52**

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 Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah St.,
Tabriz, Iran

City

Tabriz

Postal code

Approval date

2014-01-20, 1392/10/30

Ethics committee reference number

92172

Health conditions studied

1

Description of health condition studied

ovarian cancer

ICD-10 code

C56

ICD-10 code description

Malignant neoplasm of ovary

2

Description of health condition studied

lung cancer

ICD-10 code

C34

ICD-10 code description

Malignant neoplasm of bronchus and lung

Primary outcomes

1

Description

Incidence of chemotherapy-induced peripheral neuropathy

Timepoint

before the onset of chemotherapy and after 18 weeks, at the end of the treatment period

Method of measurement

rTNS Score, Nerve Conduction Study

2

Description

Severity of chemotherapy-induced peripheral neuropathy

Timepoint

before the onset of chemotherapy and after 18 weeks, at the end of the treatment period

Method of measurement

rTNS Score, Nerve Conduction Study

Secondary outcomes

1

Description

serum levels of pro-inflammatory cytokines

Timepoint

before the onset of chemotherapy and after 18 weeks at the end of treatment.

Method of measurement

ELISA

2

Description

Total Antioxidant Status (TAS)

Timepoint

before the onset of chemotherapy and after 18 weeks at the end of treatment.

Method of measurement

Spectrophotometry

3

Description

serum level of MDA

Timepoint

before the onset of chemotherapy and after 18 weeks at the end of treatment.

Method of measurement

Spectrophotometry

4

Description

activity of SOD & GPX enzymes in RBC

Timepoint

before the onset of chemotherapy and after 18 weeks at the end of treatment.

Method of measurement

Spectrophotometry

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

Supplemented group: 2 g oral ginger daily(2 one-gram tablets of ginger)for 18 weeks

Category

Prevention

2**Description**

Placebo group: 2 g oral corn starch daily(2 one-gram tablets of corn starch)for 18 weeks

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ward of Hematology & Oncology, Shahid Ghazi Hospital

Full name of responsible person

Dr. Ali Esfahani

Street address

Shahid Ghazi Tabatabaei Hospital, Daneshgah St., Tabriz, Iran

City

Tabriz

2**Recruitment center****Name of recruitment center**

University Clinic of Sheikhorraisi

Full name of responsible person

Dr. Ali Esfahani

Street address

University Clinic of Sheikhorraisi, Azadi Ave. Tabriz, Iran

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hossein Babaei

Street address

Drug Applied Research Center, Medical Research and Development Complex, Daneshgah St., Tabriz, Iran

City

Tabriz

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

Yes

Title of funding source

Drug Applied Research Center, Tabriz University of Medical Sciences

Proportion provided by this source**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

2**Sponsor****Name of organization / entity**

Nutrition Research Center, Tabriz University of Medical Sciences

Full name of responsible person

dr. Alireza Ostadrahimi

Street address

Nutrition Research Center , Faculty of Health & Nutrition, Attar St., Tabriz, Iran

City

Tabriz

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

Yes

Title of funding source

Nutrition Research Center, Tabriz University of Medical Sciences

Proportion provided by this source**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

3**Sponsor****Name of organization / entity**

Physical Medicine & Rehabilitation Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Shakouri

Street addressPhysical Medicine & Rehabilitation Research Center,
Emam Reza hospital, Tabriz, Iran**City**

Tabriz

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

Yes

Title of funding sourcePhysical Medicine & Rehabilitation Research Center,
Tabriz University of Medical Sciences**Proportion provided by this source****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***4****Sponsor****Name of organization / entity**Hematology and Oncology Research Center, Tabriz
University of Medical Sciences**Full name of responsible person**

Dr Jamal Eivazi Ziaei

Street addressHematology and Oncology Research Center, Shahid
Ghazi hospital, Tabriz, Iran**City**

Tabriz

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

Yes

Title of funding sourceHematology and Oncology Research Center, Tabriz
University of Medical Sciences**Proportion provided by this source****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**Nutrition Research Center, Tabriz University of
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Zohreh Ghoreishi

Position

Assistant Professor

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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