

# 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

Iran (Islamic Republic of)

###### Phone

+98 41 1335 2295

###### Email address

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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 address**Physical Medicine & Rehabilitation Research Center,  
Emam Reza hospital, Tabriz, Iran**City**

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

Yes

**Title of funding source**Physical 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 address**Hematology 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 source**Hematology 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

**Other areas of specialty/work****Street address**Nutrition Research Center, Faculty of Health &  
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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*