

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### he effect of ginseng on cancer related pain, and Quality of sleep in cancer survivors: a clinical trial study.

#### Protocol summary

##### Study aim

The effect of standardized ginseng extract on pain and quality of sleep in patients with cancer.

##### Design

In this study, 80 patients with gastrointestinal and intestinal cancer who are referred to the Shahid Ghazi city of Tabriz are selected. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

##### Settings and conduct

A double blind clinical trial study performed on cancer survivors referred to the Tabriz Shahid Ghazi Center in 2017-18. Participants will be randomly allocated into two groups of control and intervention using blocking method. Before the intervention, after 28 days, the pain and quality of sleep will be measured. The intervention group received 250 mg of standardized ginseng extract once a day, and was given to the placebo control group once a day. Blinding of the study by placing the drug and placebo in the same packages will be opaque.

##### Participants/Inclusion and exclusion criteria

Study Participants: Patients with gastric or colorectal cancer who complain of pain / sleep disturbance. Patients with hypertension, diabetes, history of seizures, taking aspirin or warfarin are excluded.

##### Intervention groups

Standardized Ginseng Extract

##### Main outcome variables

Reduce pain Improve sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171015036777N2**

Registration date: **2018-01-10, 1396/10/20**

Registration timing: **prospective**

Last update: **2018-01-10, 1396/10/20**

Update count: **0**

##### Registration date

2018-01-10, 1396/10/20

##### 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

##### Expected recruitment start date

2018-02-04, 1396/11/15

##### Expected recruitment end date

2018-05-22, 1397/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

he effect of ginseng on cancer related pain, and Quality of sleep in cancer survivors: a clinical trial study.

##### Public title

he effect of ginseng on cancer related pain, and Quality of sleep

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

A definitive diagnosis of cancer according to the opinion of the oncologist Patients who are at stage II and I of the disease. Patients with colorectal cancer or stomach cancer Having a sleep disorder Having pain

**Exclusion criteria:**

Use of anesthetics and narcotic drugs during study Participant's unwillingness to continue participating in the study Mental illness that is mentioned in the medical history of the patient. Receiving sleep disturbances such as diuretic drugs, antidepressants, inotropes and amphetamines at night Need for cardiopulmonary resuscitation during the intervention Mental disabilities Taking anti-coagulant drugs such as warfarin or aspirin Having diabetes and receiving anti-diabetes treatment

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is based on quadruple blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to hide the drug with a placebo, the drug will be placed in matte packets in similar envelopes.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

کمیته منطقه ای اخلاق دانشگاه علوم پزشکی تبریز

**Street address**

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabri

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165687386

**Approval date**

2017-12-04, 1396/09/13

**Ethics committee reference number**

IR.TBZMED.REC.1396.785

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

cancer

**ICD-10 code**

G89.3

**ICD-10 code description**

Neoplasm related pain (acute) (chronic)

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

Pain based on scale vas

**Timepoint**

Before the intervention, 30 days after the intervention.

**Method of measurement**

scale VAS

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

Sleep quality based on Pittsburgh scale

**Timepoint**

Before the intervention, 30 days after the intervention.

**Method of measurement**

Pittsburgh scale

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

Intervention group: Standard Jensing Extract 250 mg, Gol daru Factory, once a day

**Category**

Treatment - Drugs

**2****Description**

Control group: Capsules of the same color and shape and size with the main drug filled with placebo (wheat flour)

**Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

shahid Ghazi

**Full name of responsible person**

Azad Rahmani

**Street address**

Tabriz, Southern Shariati, Faculty of Nursing and Midwifery

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

999999

**Phone**

+98 41 3477 6411

**Email**

Musab.ghaderi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Shahid Ghazi Research Center

**Street address**

Tabriz - University Street - Golgarsh Street, Shahid Ghazi Hospital - Hematology and Oncology Research Center

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

51665-158

**Phone**

+98 41 3334 3626

**Email**

horc\_tums@tbzmed.ac.ir

**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

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Azad Rahmani

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Tabriz, Southern Shariati, Faculty of Nursing and Midwifery

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

nursing@tbzmed.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Musab Ghaderi

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Tabriz, Southern Shariati, Faculty of Nursing and Midwifery

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

musab.ghaderi@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

musab ghaderi

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Tabriz, Southern Shariati, Faculty of Nursing and Midwifery

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

Musab.ghaderi@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**

Data related to the main objectives without mentioning the personal details of individuals

**When the data will become available and for how long**

Six months after the publication of the article

**To whom data/document is available**

Individuals who intend to conduct a meta-study study or systematic review.

**Under which criteria data/document could be used**

In order to conduct a meta-analysis study

**From where data/document is obtainable**

musab.ghaderi@gmail.com

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

\*\*

**Comments**