Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ginsing 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
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Comments