Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of Spinal-Z with conventional chemotherapy on the survival of gastric and esophageal cancer patients: A randomized clinical trial

Protocol summary

Summary

Objectives: Despite advances in cancer treatment, gastric and esophageal cancer patients have a low chance of survival and current treatments are not effective enough. This study was designed to assess the efficiency of Spinal-Z medicine as a complementary therapy to current treatments in increasing the overall survival of patients with gastric and esophageal cancers. Design: This study was the phase three of a multicenter double-blind randomized clinical trial. This study was done on gastric and esophageal cancer patients at Digestive Diseases Research Institute and Hematology-Oncology, stem cell Transplantation Research Center and 12 private clinics in Tehran, Ardebil and Golestan provinces between April 2008 and April 2010. Setting: Patients were randomly assigned to intervention and control groups using a random number table. Patients in the intervention group received Spinal-Z capsule, 500/700 mg orally 2 or 3 times a day while the control group was prescribed to receive placebo with the same interval. The treating physician and patient did not know about the type of medication. Main medication and placebo were quite similar to each other. Medications were only available to the medication delivery person who had any contribution to the treatment process and collecting information. Participants: patients (age>=18) with confirmed esophageal squamous cell carcinoma or Adenocarcinoma of the distal esophagus or gastric cancer histologically. Intervention: Intervention group received 6 months of treatment with Spinal-Z, plus conventional chemotherapy and control group received conventional chemotherapy with placebo. Follow-up last 30 months. Primary outcome measure was overall survival.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092529963N1**
Registration date: **2016-12-21, 1395/10/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-21, 1395/10/01

Registrant information

Name
Alireza Sadjadi
Name of organization / entity
Digestive Diseases Research Institute
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Digestive Diseases Research Institute, Tehran University of Medical Sciences

Expected recruitment start date

2008-04-01, 1387/01/13

Expected recruitment end date

2010-04-01, 1389/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of Spinal-Z with conventional chemotherapy on the survival of gastric and esophageal cancer patients: A randomized clinical trial

Public title
An herbal medication as complementary conventional chemotherapy for gastric and esophageal cancer patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Histologically confirmed esophageal squamous cell carcinoma or Adenocarcinoma of the distal esophagus or gastric cancer; The Largest diameter of the lesion ≥ 10 mm based on Spiral-CT Scan; The absence of brain metastases; Karnofsky Performance status scale ≥70%; Age>=18 Exclusion criteria: Congestive heart failure (EF <= 40%); Medical history of myocardial infarction during the past 6 months; Concurrent use of Vasodilators; Uncontrolled arrhythmias; Complications in central nervous system (Spinal cord and brain); Medical history of CVA, stroke within the last 6 months; Respiratory failure (PO2<= 50 mmHg) for any reason; Level of liver enzymes (AST, ALT) > 5 folds the normal limits; Bilirubin serum ≥ 5 mg per deciliter; serum Creatinine level > 2 milligrams per deciliter); WBC < 2500 per cubic millimeter of blood; Platelet count < 100,000 per cubic millimeter of blood ; Pregnant and nursing mothers; Any type of active infection ; IV drug users ; Major psychological disorders

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **83**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Patients were randomly assigned to intervention and control groups using a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Digestive Diseases Research Institute, Tehran university of Medical Sciences

Street address
Shariati Hospital, Kargar Shomali Avenue, Tehran

City
Tehran

Postal code
1411713135

Approval date
2005-10-20, 1384/07/28

Ethics committee reference number
418/184

Health conditions studied

1

Description of health condition studied
Oesophagus cancer

ICD-10 code
C15

ICD-10 code description
Malignant neoplasm of oesophagus

2

Description of health condition studied
Gastric cancer

ICD-10 code
C16

ICD-10 code description
Malignant neoplasm of stomach

Primary outcomes

1

Description
Overall survival

Timepoint
30 months

Method of measurement
Patients were visited in 0, 8 and 24 weeks after the beginning of intervention, and their health status was evaluated. Patients then were followed up via telephone contacts and cancer registry data.

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Intervention group: patients was treated with conventional chemotherapy plus Spinal-Z. Patients received 500 or 700 mg Spinal-Z oral capsules, 2 or 3 times a day. The spinal-Z capsule was manufactured by Darou Pakhsh company registered German patent No 196-31-681-2. Spinal-Z is a mixture of two plants: Peganum harmala Linn seeds and Dracocephalum kotschyi Boiss leave.
Category
Treatment - Drugs

2

Description
Control group: Patients received conventional chemotherapy plus placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Digestive Diseases Research Institute
Full name of responsible person
Dr Alireza Sadjadi
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2

Recruitment center
Name of recruitment center
Hemotology and Oncology and Stem Cell Transplantation Research Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research ,Digestive Diseases Research Institute, Tehran University of Medical Sc
Full name of responsible person
Dr Hossein Poustchi
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Shariati Hospital, Kargar Shomali Ave, Tehran
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Grant name
123700006
Grant code / Reference number
123700006
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research ,Digestive Diseases Research Institute, Tehran University of Medical Sc
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
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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