

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 $\geq$ 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8241 5102

Email address

sadjadi@ddrc.ac.ir

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 $\geq 70\%$; Age ≥ 18 Exclusion criteria: Congestive heart failure (EF $\leq 40\%$); 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

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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 kotschy 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

Street address

Shariati Hospital, Kargar Shomali Ave, Tehran

City

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2

Recruitment center

Name of recruitment center

Hematology and Oncology and Stem Cell Transplantation Research Center

Full name of responsible person

Dr Alireza Sadjadi

Street address

Shariati Hospital, Kargar Shomali Avenue, Tehran

City

Tehran

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

Street address

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

Name of organization / entity

Digestive Diseases Research Institute

Full name of responsible person

Asieh Shahrabi Farahani

Position

researcher

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Alireza Sajadi

Position

Doctor of medicine

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Web page address**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

Person responsible for updating data**Contact****Name of organization / entity**

Digestive Diseases Research Institute

Full name of responsible person

Asieh Shahrabi Farahani

Position

researcher

Other areas of specialty/work**Street address**

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