

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Efficacy of Spinal-Z compared with placebo in metastatic gastric adenocarcinoma

Protocol summary

Summary

This study is a single blind, clinical trial that evaluates the effects of Spinal-z on patients with metastatic gastric adenocarcinoma. The Patients who enter this study are between 15 and 65 years old and they have received pathologic diagnosis of gastric adenocarcinoma (stage 4). The Patients with creatinine over than 2 or Ejection Fraction less than 45%, are excluded from the study. About 78 patients are evaluated in this study. The patients are divided randomly interventional and control. The patients do not know about 2 group interventional and control (single blind). The patients in interventional group are treated by 6 Spinal-z capsules daily (2 capsules after breakfast, 2 capsules after lunch and 2 capsules after dinner). The control group is treated by 6 capsules of placebo in the same order. There is no difference between placebo and spinal-z capsules in shape, weight, color, taste and odor. The patients are visited and evaluated once every three weeks for 3 months. The patients are evaluated for digestive signs (dysphagia, abdominal pain and anorexia), itching, nausea, vomiting, Blood urea nitrogen, creatinine, fasting blood sugar, blood pressure, heart rate, hemoglobin, platelets, white blood cells, and their liver enzymes are evaluated every 6 weeks. Digestive signs scale from 0 to 10 score and according to this scaling, patients are divided to, mild (1-3), moderate (4-6), severe (7-10) and zero (0). The patients are excluded from the study in case of exposure to severe complications, or disagreement to carry on the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010111967N1**

Registration date: **2013-03-03, 1391/12/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-03, 1391/12/13

Registrant information

Name

Alireza Ghanbaran

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 1337 7065

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ghanbaran.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz JundiShapur University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Spinal-Z compared with placebo in metastatic gastric adenocarcinoma

Public title

The effect of Spinal-z in gastric adenocarcinoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The Patients who enter this study are between 15 and 65 years old and they have received pathologic diagnosis of gastric adenocarcinoma (stage 4)
Exclusion criteria: Patients with creatinine over than 2 and Ejection Fraction less than 45% and exposure to severe complications.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Ahvaz Jundishapur University of Medical Sciences

Street address

Ethics Committee, Ahvaz Jundishapur University of Medical Sciences, Golestan Street, Ahvaz

City

Ahvaz

Postal code

61357-15794

Approval date

2012-10-27, 1391/08/06

Ethics committee reference number

ETH-639

Health conditions studied

1

Description of health condition studied

Gastric adenocarcinoma

ICD-10 code

c16,c16-1,

ICD-10 code description

Neoplasm of stomach. cardia. body. pyloric. lesser curvature of stomach. Greater curvature of stomach

Primary outcomes

1

Description

Dysphagia

Timepoint

Every 3 weeks until 3 months

Method of measurement

Questionnaire

2

Description

Abdominal pain

Timepoint

Every 3 weeks until 3 months

Method of measurement

Questionnaire

3

Description

Anorexia

Timepoint

Every 3 weeks until 3 months

Method of measurement

Questionnaire

4

Description

Glomerular filtration rate(GFR)

Timepoint

Every 3 weeks until 3 months

Method of measurement

Cockcroft-Gault: $\text{CrCl (mL/min)} = (140 - \text{age (years)}) \times \text{weight (kg)} \times [0.85 \text{ if female}] / (72 \times \text{sCr (mg/dL)})$

5

Description

Fasting blood sugar

Timepoint

Every 3 weeks until 3 months

Method of measurement

Laboratory kit of blood sugar

6

Description

Blood pressure

Timepoint

Every 3 weeks until 3 months

Method of measurement

Mercury Sphyngomanometer

7

Description

Hemoglobin

Timepoint

Every 3 weeks until 3 months

Method of measurement

Hemoglobinometer(with cyanmethemoglobin)

8

Description

Liver enzymes

Timepoint

Every 6 weeks until 3 months

Method of measurement

Laboratory kit of liver enzymes

9

Description

Erythrocyte sedimentation rate(ESR)

Timepoint

Every 6 weeks until 3 months

Method of measurement

Westergren(laboratory method)

10

Description

Platelets

Timepoint

Every 3 weeks until 3 months

Method of measurement

Electronics impedance(laboratory method)

11

Description

White blood cells

Timepoint

Every 3 weeks until 3 months

Method of measurement

Electronics impedance(laboratory method)

Secondary outcomes

1

Description

Vomiting

Timepoint

Every 3 weeks until 3 months

Method of measurement

Questionnaire

2

Description

Itching

Timepoint

Every 3 weeks until 3 months

Method of measurement

Questionnaire

3

Description

Nausea

Timepoint

Every 3 weeks until 3 months

Method of measurement

Questionnaire

Intervention groups

1

Description

The patients in interventional group are treated by 6 Spinal-z capsules daily (2 capsules after breakfast, 2 capsules after lunch and 2 capsules after dinner) for 3 months. Spinal-z capsules is a botanical medicine. Each capsule contains the essence of the Peganum Harmala Linn. Its most effective substance is B- carboline alkaloids, which can control and restrain the duplication of malignant cells, and is produced by Daroupakhsh MFG company.

Category

Treatment - Drugs

2

Description

The patients in control group are treated by 6 placebo Capsules daily(2 capsules after breakfast, 2 capsules after lunch and 2 capsules after dinner) for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Ehsanpour. Ali, MD

Street address

Shafa Hospital, Golestan Street, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz JundiShapur University of Medical Sciences

Full name of responsible person

Feghei, MD

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Vice chancellor for research, Ahvaz JundiShapur
University of Medical Sciences, Golestan Street,
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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

Vice chancellor for research, Ahvaz JundiShapur
University of Medical Sciences

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ehsanpour. Ali, MD

Position

Internist

Other areas of specialty/work

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Person responsible for updating data

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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