

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of the efficacy and safety of Spinal-Z on clinical symptom of the patients with cancer of the upper part of the gastrointestinal tract

Protocol summary

Summary

Objectives: Evaluation of the efficacy and safety of spinal-Z on patients with cancer of the upper part of the gastrointestinal tract. Design: Prospective double blind clinical trial. The study population consist of 61 patients in 2 groups (Treatment and control). Participants: Patients with cancer of the upper part of the gastrointestinal tract without concurrent diseases, metastasis and Abnormal liver and kidney function tests. Intervention: Administration of 600 mg/m² of oral Spinal-Z per day in the treatment group and placebo in the control group. Main outcome: Quality of life, Demographic data, Length of cancer, Type of cancer, Family background, Abdominal pain, Burn heart, Constipation, Vomiting and Drug adverse effects.

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences

Expected recruitment start date

2010-04-11, 1389/01/22

Expected recruitment end date

2011-04-10, 1390/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612051165N15**

Registration date: **2017-03-01, 1395/12/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Scientific title

Evaluation of the efficacy and safety of Spinal-Z on clinical symptom of the patients with cancer of the upper part of the gastrointestinal tract

Public title

Evaluation of the efficacy of Spinal-Z on patients with gastrointestinal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient with age of 25-75 year-old; Patients with gastric adenocarcinoma or Esophageal squamous cell carcinoma with standard treatment during the study; No sign of metastasis in the patients.

Exclusion criteria: Participate in the study with use of any other drugs; history of bone marrow or stem cells transplants; Comorbidities include active infection, respiratory failure, heart failure or left ventricular EF <50%, inflammatory disorders, including rheumatoid arthritis and gout false, thyroid disorders or a history of thyroid antibodies, hyperviscosity syndrome, osteoporosis, anemia, bone marrow disorders such as

sickle cell form, thalassemia or myelodysplastic syndrome, immune deficiency and psychiatric diseases that decreases the patient's tolerance; Pregnancy or lactation; Serum creatinine more than 1.5 times the maximum amount of the normal range; AST and ALT more than 1.5 times the upper limit of normal; Alkaline phosphatase greater than 2.5 times the upper limit of the normal range; Bilirubin more than 1.5 mg/dl.

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **61**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

N/A

Secondary Ids

empty

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

Baqiyatallah University of Medical Sciences

Street address

Molla sadra st., Sheikhabahee St.,

City

Tehran

Postal code**Approval date**

2010-02-21, 1388/12/02

Ethics committee reference number

IR.BMSU.REC.1388.2

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

Gastrointestinal Cancer

ICD-10 code

C26.9

ICD-10 code description

Malignant neoplasm: Ill-defined sites within the digestive system

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

Type of cancer

Timepoint

Before and after of intervention

Method of measurement

Examination and Diagnostic procedures

2**Description**

Length of the cancer

Timepoint

During the study

Method of measurement

Examination and Diagnostic procedures

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

Pathology

Timepoint

Before and after of intervention

Method of measurement

Laboratory

2**Description**

Drug Adverse effects

Timepoint

During the study

Method of measurement

History and physical examination

3**Description**

Quality of life

Timepoint

Before and after of intervention

Method of measurement

Questionnaire

4**Description**

Gastrointestinal signs: Abdominal pain, Heart burn, Constipation and vomiting

Timepoint

Before and after of intervention

Method of measurement

History and physical examination

Intervention groups

1

Description

In the treatment group administration of Spinal-Z to the treatment group in addition to the standard treatment.

Category

Treatment - Drugs

2

Description

In the control group administration of the placebo in addition of standard treatments

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah University of Medical Sciences Hospital

Full name of responsible person

Dr. Yunes Panahi

Street address

Mollasadra St., Sheykhbahaee St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr. Yunes Panahi

Street address

Mollasadra St., Sheykhbahaee St.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Baqiyatallah 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

Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr. Yunes Panahi

Position

Critical care Pharmacotherapy, Professor

Other areas of specialty/work

Street address

Mollasadra St., Sheykhbahaee St.

City

Tehran

Postal code

Phone

+98 21 8821 1524

Fax

Email

yunespanahi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr. Yunes Panahi

Position

Critical care Pharmacotherapy, Professor

Other areas of specialty/work

Street address

Mollasadra St., Sheykhbahaee St.

City

Tehran

Postal code

Phone

+98 21 8821 1524

Fax

Email

yunespanahi@yahoo.com

Web page address

Person responsible for updating data

Contact

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