# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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.

## 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

**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

**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., Sheikhbahaee 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., Sheykhbahae 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**
Molasadra 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*