

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison between zinc sulphate and placebo capsules in the prevention of mucositis in patients with leukemia under chemotherapy: a clinical trial study

#### Protocol summary

##### Summary

The present study was a randomized, controlled trial examining the effect of zinc sulphate in preventing of mucositis in patients with leukemia under chemotherapy. The inclusion criteria of the study were leukemia patients with  $\geq 18$  years old or above, under chemotherapy, be alerted and oriented, and able to swallow capsule and did not show the mucositis symptoms such as ulcers, erythema, oedema, painful and dysphasia. The patients with any ulcer in their mouth, pregnant and lactating women, individuals under head and neck radiotherapy and patients who had the allergic to zinc were excluded from the study. The participants were allocated into the intervention (zinc sulphate) or the control group (placebo capsules) by block randomization with a random sequence of 2 or 4 block sizes. In this study, the patients remained blind to their allocation into the intervention and control groups. The researcher assistant who collected the data was also blind to the study groups. Moreover, the person who performed the data analysis was kept blinded to the allocation. The sample size was 86 patients (43 in each group). Both groups received either zinc sulfate (50 mg) or placebo capsules three times daily for 14 days from the first day of chemotherapy. The mucositis was measured by JP Donnelly and Colleagues questionnaire and World Health Organization mucositis scale in fourth, seventh and 14th day of starting chemotherapy.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014012713690N2**

Registration date: **2014-03-08, 1392/12/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-03-08, 1392/12/17

##### Registrant information

###### Name

Masoume Rambod

###### Name of organization / entity

Shiraz University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4258

###### Email address

rambodm@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research affairs of Shiraz University of Medical Science

##### Expected recruitment start date

2012-04-01, 1391/01/13

##### Expected recruitment end date

2014-04-04, 1393/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison between zinc sulphate and placebo capsules in the prevention of mucositis in patients with leukemia under chemotherapy: a clinical trial study

##### Public title

Effect of zinc sulphate on mucositis.

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

The inclusion criteria of the study were leukemia patients with  $\geq 18$  years old or above, under chemotherapy, be alerted and oriented, and able to swallow capsule and did not show the mucositis symptoms such as ulcers, erythema, oedema, painful and dysphasia. The patients with any ulcer in their mouth, pregnant and lactating women, individuals under head and neck radiotherapy and patients who had the allergic to zinc were excluded from the study.

### **Age**

From **18 years** old to **100 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **86**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Triple blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shiraz University of Medical Science

##### **Street address**

Vice chancellor for research affairs, seven floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2010-02-01, 1388/11/12

#### **Ethics committee reference number**

491488 م ت

## **Health conditions studied**

### 1

#### **Description of health condition studied**

leukaemia

#### **ICD-10 code**

C91, C92

#### **ICD-10 code description**

Lymphoid leukaemia, Myeloid leukaemia

## **Primary outcomes**

### 1

#### **Description**

Mucositis

#### **Timepoint**

Fourth, seventh, 14th day from starting chemotherapy

#### **Method of measurement**

JP Donnelly and Colleagues questionnaire, and World Health Organization mucositis scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: administration of 50 mg zinc sulphate capsule, three times daily for 14 days from the first day of chemotherapy.

#### **Category**

Prevention

### 2

#### **Description**

Control group: administration of placebo capsules, three times daily for 14 days from the first day of chemotherapy.

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Namazee Teaching Hospital

##### **Full name of responsible person**

##### **Street address**

##### **City**

Shiraz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Vice chancellor for research affairs of Shiraz  
University of Medical Science

**Full name of responsible person**

Dr Gholamreza Hatam

**Street address**

Vice chancellor for research affairs, seven floor,  
Shiraz University of Medical Science, beside helal  
Ahmar, Zand street, Shiraz

**City**

Shiraz

**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 affairs of Shiraz University of  
Medical Science

**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**

Shiraz University of Medical Science

**Full name of responsible person**

Masoume Rambod

**Position**

M.S.

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

Nursing and Midwifery University, Namazee Sq, Zand  
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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*