

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 ≥ 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 ≥ 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**

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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