

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Efficacy of systemic zinc sulphate in prevention of chemotherapy-induced mucositis in patients with leukemia

Protocol summary

Summary

1. Purpose of study: the evaluation of systemic prescriptin of zinc sulphate in prevention of chemotherapy-induced mucositis in patirnts with leukemia. 2. Performing design of study: this 6 month study will be performed in two case & study groups of patients with leukemia refering to oncology ward of Tabriz shahid ghazi hospital. 3. Inclusion criteria: patients within range of 18-71 years old hospitalizing in oncology ward of Tabriz shahid ghazi hospital undergoing chemotherapy due to leukemia. 4. Exclusion criteria: patients who have other systemic diseases; existence of any oral ulcers or mucositis before the beginning chemotherapy; experience of drug sensitivity. 5. Sample size: 140 patients with leukemia would be divided into two equal groups. 6. Interventios case group: zinc sulphate with 220mg/kg dosage would be prescribed during chemotherapy. 7. Intervention time: during chemotherapy. 8. Studied outcomes: The incidence & severity of chemotherapy-induced mucositis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042312510N2**

Registration date: **2013-08-03, 1392/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-03, 1392/05/12

Registrant information

Name

Narges Gholizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tooth and gingiva diseases research center, Tabriz, Iran

Expected recruitment start date

2013-04-28, 1392/02/08

Expected recruitment end date

2013-09-10, 1392/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of systemic zinc sulphate in prevention of chemotherapy-induced mucositis in patients with leukemia

Public title

Efficacy of systemic zinc sulphate in prevention of chemotherapy-induced mucositis in patients with leukemia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients within range of 18-71 years old hospitalizing in oncology ward of Tabriz shahid ghazi hospital(Tabriz, Iran) undergoing chemotherapy due to leukemia. Exclusion criteria: patients who have other systemic diseases; existence of any oral ulcers or mucositis before the beginning chemotherapy;

experience of drug sensitivity.

Age

From **18 years** old to **71 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz university of medical sciences

Street address

Tabriz, Golgasht st, Tabriz university of medical sciences, No 2 central building, 3th floor

City

Tabriz

Postal code

Approval date

2013-04-21, 1392/02/01

Ethics committee reference number

9267

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C90.1

ICD-10 code description

Plasmacytic leukemia

Primary outcomes

1

Description

Mucositis

Timepoint

2& 4 weeks after chemotherapy

Method of measurement

Index of WHO

Secondary outcomes

1

Description

Allergy to drug

Timepoint

One day after drug prescription for one month

Method of measurement

Clinical examination

Intervention groups

1

Description

Prescription of zinc sulphate(PO) in case group by oncologist during chemotherapy protocol with 220mg/kg dosage would be performed

Category

Treatment - Drugs

2

Description

prescription of Multivitamin drug(PO) in control group by oncologist during chemotherapy protocol and the once daily for patients would be performed

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid ghazi hospital

Full name of responsible person

Hadi chavoshi

Street address

Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Seid Kazem Shakouri

Street address

Tabriz University of Medical Sciences, Golgasht

City

Tabriz

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, Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Narges Gholizadeh

Position

Oral medicine specialist, assistance professor

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Tabriz University of Medical Sciences

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Tabriz Dental Faculty

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Fax**Email****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*