

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 41 1335 5968

Email address

n.gholizadeh88@gmail.com

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

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

Dentistry faculty, Tabriz University of Medical Sciences, Golgasht St.

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Fax**Email**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Chavoshi

Position

Oncology specialist

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

Tabriz University of Medical Sciences, Shahid Ghazi hospital

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chavoshi-h@yahoo.com

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz Dental Faculty

Full name of responsible person

Sirwan Kahani

Position

Undergraduated student

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

Golgasht st, Dental faculty

City

Tabriz

Postal code

57819-17193

Phone

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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