Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of zinc sulfate effect in prevention of chemotherapy-induced mucositis in Patients with cancer referred to Emam Ali Hospital in 2008-2009

Protocol summary

Summary

This study has been designed to evaluate the effect of zinc Sulphate in prevention of chemotherapy-induced mucositis. A total of 50 patients with chemotherapy-induced mucositis are randomly assigned into intervention or control group. The intervention group received three zinc sulfate capsules daily (220-mg made by Alhavi Co.) in addition to conventional mucositis treatment and the control group received three placebo capsules daily. for 6 months. Intensity of Mucositis, Xerostomia, and pain are evaluated a week before initiation of chemotherapy, during chemotherapy phase until two weeks after the end of chemotherapy phase, once a week compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101023133N3**
Registration date: **2011-02-01, 1389/11/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-02-01, 1389/11/12

Registrant information

Name

Fateme Arbabi Kalati

Name of organization / entity

Dental school of Zahedan

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 1814

Email address

farbabi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2008-08-22, 1387/06/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of zinc sulfate effect in prevention of chemotherapy-induced mucositis in Patients with cancer referred to Emam Ali Hospital in 2008-2009

Public title

Evaluation of zinc sulfate effect in prevention of chemotherapy-induced mucositis in Patients with cancer referred to Emam Ali Hospital in 2008-2009

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: chemotherapy treatment with a regimen that had the same mucositis probability, Karnovsky performance status case equal or more than 60, life expectancy equal to or more than 6 months, White Blood Cell count equal to or more than 1500 and platelet count equal to or more than 100000/µL Exclusion criteria: radiotherapy in the head and neck region, including nasopharynx, oropharynx, and larynx previously or simultaneously, previous head and neck

surgery due to malignancy, use of dentures, pregnancy, infection

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Pardis, Zahedan

City
Zahedan

Postal code

Approval date
2010-12-29, 1389/10/08

Ethics committee reference number
89-2870

Health conditions studied

1

Description of health condition studied
Chemotherapy-induced mucositis

ICD-10 code
K13.7

ICD-10 code description
Other and unspecified lesions of oral mucosa

Primary outcomes

1

Description
Mucositis

Timepoint
Two weeks after initiation of chemotherapy and every two weeks until

Method of measurement
The patients are examined under a headlight, using dental explorers and mirrors. Data were recorded. Oral mucositis patients were labelled from 0 to 4 ,using World Health.

Secondary outcomes

1

Description
Pain

Timepoint
Two weeks after initiation of chemotherapy and every two weeks untilthe end of chemotherapy phase

Method of measurement
The patients are examined under a headlight, using dental explorers and mirrors. Data were recorded. Oral mucositis patients were labelled from 0 to 4 ,using World Health.

2

Description
Xerostomia

Timepoint
Two weeks after initiation of chemotherapy and every two weeks untilthe end of chemotherapy phase

Method of measurement
The patients are examined under a headlight, using dental explorers and mirrors. Data were recorded

3

Description
Quality of life

Timepoint
Two weeks after initiation of chemotherapy and every two weeks untilthe end of chemotherapy phase

Method of measurement
Quality of life a questionnaire(EORTC LQ-OES18) is filled out each meeting individually by the dental student

Intervention groups

1

Description
Control group/Placebo: three placebo capsules daily (Alhavi Co.), initiation of chemotherapy until the end of chemotherapy phase.

Category
Prevention

2

Description
Intervention group/Drug: three 220-mg zinc sulfate capsules daily (Alhavi Co.), initiation of chemotherapy until the end of chemotherapy phase
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan Emam Ali Hospital
Full name of responsible person
Fateme Arbabi-kalati(assistant of professor ,a specialist of oral medicine)
Street address
Emam Ali Hospital-Zahedan
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr sagheb (Vice-chancellor for Research, Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences, Pardis, Khalij Fars Boulevard, Zahedan
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Marzie Deghatipour
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Other areas of specialty/work
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Person responsible for updating data

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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