

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the effect of oral zinc sulfate with placebo on the prevention of chemotherapy-induced oral mucositis in patients treated with adriamycin and cyclophosphamide

Protocol summary

Study aim

Determining and comparing the effect of oral zinc sulfate with placebo on the prevention of chemotherapy-induced oral mucositis

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 92 patients

Settings and conduct

In this randomized double-blind clinical trial study, 92 patients with cancer who are candidates for chemotherapy containing adriamycin and cyclophosphamide referred to Seyed Al-Shohada Hospital in Isfahan will be randomly divided into two groups. One group will receive zinc sulfate and the other group will receive a placebo. Then the incidence of oral mucositis, pain and quality of life of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria included cancer (based on biopsy), candidate for chemotherapy containing adriamycin and cyclophosphamide, having normal serum zinc levels, and consent to participate in the study. Exclusion criteria are pre-study oral mucositis.

Intervention groups

Intervention group: when starting chemotherapy treatment, patients take two capsules of zinc sulfate (Alhavi Company) daily with food for 12 weeks. Control group: when starting chemotherapy treatment, patients take two placebo capsules (Alhavi Company) daily with food for 12 weeks.

Main outcome variables

Incidence of oral mucositis; the pain; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150304021338N2**

Registration date: **2021-02-11, 1399/11/23**

Registration timing: **prospective**

Last update: **2021-02-11, 1399/11/23**

Update count: **0**

Registration date

2021-02-11, 1399/11/23

Registrant information

Name

Mahnaz Roayaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 7396

Email address

roayaei@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-18, 1399/11/30

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral zinc sulfate with placebo

on the prevention of chemotherapy-induced oral mucositis in patients treated with adriamycin and cyclophosphamide

Public title

Comparison of the effect of oral zinc sulfate on the prevention of chemotherapy-induced oral mucositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a biopsy-confirmed cancer. Candidate for chemotherapy containing adriamycin and cyclophosphamide Having a normal serum zinc level Satisfaction to participate in the study

Exclusion criteria:

Infection of the oral mucosa before the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: 92

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, two drugs, oral zinc sulfate and placebo, in terms of shape and color, are prepared in the same way and provided to the researcher. They also prescribe them without knowing the type of any of the drugs. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Center of Medical Research - Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81745319

Approval date

2020-07-03, 1399/04/13

Ethics committee reference number

IR.MUI.MED.REC.1399.277

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description

Pain

Timepoint

Before starting chemotherapy and once every three weeks for up to 12 weeks

Method of measurement

Visual Analog Scale (VAS)

2

Description

Incidence of oral mucositis

Timepoint

Before starting chemotherapy and once every three weeks for up to 12 weeks

Method of measurement

Observation

3

Description

Quality of Life

Timepoint

Before starting chemotherapy and once every three weeks for up to 12 weeks

Method of measurement

Cancer Patients Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: when starting chemotherapy treatment, patients take two placebo capsules(Alhavi Company) daily with food for 12 weeks.

Category

Placebo

2

Description

Intervention group: when starting chemotherapy treatment, patients take two capsules of zinc sulfate (Alhavi Company) daily with food for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyed-Al-Shohada Hospital

Full name of responsible person

Dr. Mahnaz Roayaei

Street address

Sayyed-Al-Shohada Hospital, Motahari Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahnaz Roayaei

Position

Assistant Professor / PhD in Radiotherapist

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Zeinab Andalib

Position

Assistant Professor / PhD in Radiotherapist

Latest degree

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Other areas of specialty/work

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