

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 31 3235 0210

##### Email

roayaei@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjoo Javanmard

##### Street address

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

##### City

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##### Postal code

8174673461

##### Phone

+98 31 3668 8597

##### Email

dean@med.mui.ac.ir

##### 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

##### Street address

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Roayaei@med.mui.ac.ir

##### Web page address

## Person responsible for scientific 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**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zeinab Andalib

**Position**

Assistant Professor / PhD in Radiotherapist

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

**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