

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of prophylactic effect of alpha lipoic acid on oral mucositis in patients undergoing head and neck radiotherapy

Protocol summary

Study aim

General purpose Preventive effect of alpha lipoic acid on oral mucositis in patients receiving head and neck radiotherapy

Design

The trial has a control group, with a parallel group, double-blind, randomized, phase 3 on 30 patients. Six random blocks are used for randomization using Excel software.

Settings and conduct

In ShahadaTajrish Hospital, 30 cancer patients are undergoing radiotherapy. We give the original and placebo capsules, which are similar and have been coded by the supervisor, to the patients, and we ask them to take them during radiotherapy and up to 2 weeks after completion. use the medicine. The symptoms of mucovites are checked weekly by the resident.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with oral and nasopharyngeal cancer treated with a total dose of 5600-7000 cGy

Exclusion criteria: Lack of cooperation or willingness of the patient to continue treatment History of allergies to alpha-lipoic acid or other antioxidants and dietary supplements Pregnant or lactating women.

Intervention groups

Alpha lipoic acid capsules were given to the intervention group to consume two 300 mg capsules twice a day during the radiotherapy treatment and two weeks after that. And for the control group, placebo capsules are prescribed in the same way. In addition, both groups of patients receive treatment with normal saline mouthwash twice a day during their treatment until two weeks after radiotherapy treatment.

Main outcome variables

Degree of mucositis

General information

Reason for update

Acronym

ALA روی RIOM اثر پیشگیری کننده

IRCT registration information

IRCT registration number: **IRCT20220607055099N1**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2024-05-09, 1403/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prophylactic effect of alpha lipoic acid on oral mucositis in patients undergoing head and neck

radiotherapy

Public title

Evaluation of prophylactic effect of alpha lipoic acid on oral mucositis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with oral and nasopharyngeal cancer treated with a total radiation dose of 5600-7000 cGy

Exclusion criteria:

Pregnant patients Patients under 18 years old Patients with diabetes, thyroid disease, and liver disease Alcohol users

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **15**

The intervention and control groups each have 15 patients

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients to two groups of 15 intervention (alpha-lipoic acid) and control group (methylcellulose) is based on six random blocks using Excel software. To obtain the number of samples according to $SD1 = 0.13$ and $SD2 = 0.2$ in the study of Kakoie et al. and with $\alpha = 0.05$, $B = 0.1$ and power = 80% in order to detect a 0.2 difference between the two groups with a number of 15 samples in each We need a group. $n = (Z\alpha/2 + Z\beta)^2 \times (SD1 + SD2)^2 / d^2$ The assignment of patients to the intervention and control groups is done by randomization, which was explained, so that the patients are not aware of the contents of the given capsule. Due to the similarity between the weight, color, and shape of the drugs, the possibility of informing the patients is minimized. The drugs are divided into two groups A and B by the supervisor, and the person who is in charge of the examination and delivery of the drugs and the follow-up of the patients at the same time (resident of oral, jaw and facial diseases) is unaware of the contents of A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is done in a double blind way. The assignment of patients to the intervention and control groups is done by randomization so that the patients are not aware of the contents of the given capsule. Due to the similarities between the weight, color, and shape of the drugs, the

possibility of informing the patients is minimized. The drugs are divided into two groups A and B by the supervisor, and the person who is in charge of the examination and delivery of the drugs and the follow-up of the patients at the same time (resident of oral, jaw and facial diseases) is unaware of the contents of A and B.

Placebo

Used

Assignment

Other

Other design features

The main drug (alpha lipoic acid) was given to the intervention group in this study. Placebo was assigned to the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti Research Institute of Dental Sciences

Street address

Shahid Beheshti Faculty of Dentistry, Evin

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Province

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Postal code

1983969411

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.SBMU.DRC.REC.1401.017

Health conditions studied

1

Description of health condition studied

Oral mucositis

ICD-10 code

K12.30

ICD-10 code description

Oral mucositis

Primary outcomes

1

Description

Degree of mucositis

Timepoint

Weekly from the first day of radiotherapy to 2 weeks after radiotherapy

Method of measurement

According to the clinical criteria of the World Health

Organization

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: alpha lipoic acid capsules 300 mg twice a day, 2 capsules each time during radiotherapy sessions to be consumed by the patients for two weeks afterwards. Alpha lipoic acid (Raha Pharmaceutical Company): is one of the vitamin-like chemical substances that has an antioxidant function, in the sense that it destroys the toxic radicals created in the body.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye tajrish hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Reha Pharmaceutical Company

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam jarahzade

Position

Oral medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Not applicable

When the data will become available and for how long

As soon as the thesis is defended and the article is published, the data will be accessed.

To whom data/document is available

If the article is open access, people can access it by referring to the desired sites.

Under which criteria data/document could be used

Not applicable

From where data/document is obtainable

Author and researcher of this project Maryam Jarahzadeh with email address maryam.jarahzade92@gmail.com

What processes are involved for a request to access data/document

Not applicable

Comments