Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluaton 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
RIOM روی ALA 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

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

radiotherapy

Public title
Evaluaton 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 α = 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=(Zα/2+Zβ)2×(SD1 +SD2)2/d2 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 (alphalipoic 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
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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. Alphalipoic 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

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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
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Full name of responsible person
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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