

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Investigation The effect of alpha-lipoid acid on saliva rate of the patients underwent radiotherapy of head and neck cancers

#### Protocol summary

##### Study aim

The effect of alpha-lipoid acid on saliva rate of the patients underwent radiotherapy of head and neck cancers

##### Design

A clinical trial with a control group, double-blind, randomized, phase3 on 30 patients, was used to randomize the design of six random blocks and using Excel software.

##### Settings and conduct

The number of 30 patients with various head and neck cancers . Randomly dividing patients into two groups of 15 intervention (alphalipoic acid) and control group Examination on the first day before radiotherapy and 2-6-8-12 weeks after radiotherapy Examinations include checking the amount of unstimulated saliva and collecting saliva in falcon tubes within 5 minutes. Sampling in Tajrish Martyrs Hospital. double blind

##### Participants/Inclusion and exclusion criteria

over 18 years old and suffering from head and neck cancers with a total radiation dose of 56-70 Gy. Conditions of non-entry: history of liver disease, diabetes, thyroid, history of alcohol consumption, malnutrition, receiving any chemotherapy drugs, people who have had salivary gland cancer, treated with consumption of iron products and pregnant or lactating women

##### Intervention groups

examined on the first day and before and in 2-6-8-12 weeks after radiotherapy. Examinations on the first day will include measuring the amount of unstimulated saliva and collecting it within 5 minutes. . In this session, ALA capsules or placebo are provided to the patients of two groups to consume before starting radiotherapy. Alpha lipoic acid 300 mg capsules. The consumption of this capsule is for 3 months, and the patients of this group will consume two Alpic capsules twice a day (morning-evening) each time

##### Main outcome variables

Prevention of dry mouth and complications related to salivary glands after radiotherapy in head and neck cancer patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221219056864N1**

Registration date: **2023-07-13, 1402/04/22**

Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**

Update count: **0**

##### Registration date

2023-07-13, 1402/04/22

##### Registrant information

##### Name

Masume Heydari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8811 5352

##### Email address

heydari.s370@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-10-23, 1402/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigation The effect of alpha-lipoid acid on saliva rate of the patients underwent radiotherapy of head and neck cancers

**Public title**  
Investigating the effect of alpha lipoic acid on the amount of saliva in head and neck cancer patients undergoing radiotherapy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Age>18 Patients with head and neck cancers with a total radiation dose of 56-70 Gy  
**Exclusion criteria:**  
 History of liver disease, diabetes, thyroid History of alcohol consumption Malnutrition Receiving any chemotherapy drugs History of salivary gland cancer History of treatment with alpha-lipoid acid for any other reason History of allergy to alpha-lipoid acid or other antioxidants and food supplements Consumption of iron products Pregnant or lactating women

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients are randomly divided into two groups of 15 person with intervention (alpha lipoid acid) and control group (placebo). This work was done using the six-person random block design and using Excel software, and it is done in such a way that each person examined in the research is assigned to one of the intervention and control groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The drugs are divided into two groups A and B by the supervisor, and the person who is in charge of examining and delivering the drugs and following up the patients at the same time (resident of oral and maxillofacial diseases) will be unaware of the contents of A and B

**Placebo**  
Used

**Assignment**  
Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Organizational Committee of Biomedical Research  
Ethics in Dental Sciences

##### Street address

Valenjak Blvd. Student of Shahid Beheshti Dental  
Faculty

##### City

tehran

##### Province

Tehran

##### Postal code

1983963113

#### Approval date

2022-11-14, 1401/08/23

#### Ethics committee reference number

IR.SBMU.RDC.REC.1401.062

## Health conditions studied

### 1

#### Description of health condition studied

Cancer patients undergoing cervical radiotherapy

#### ICD-10 code

2

#### ICD-10 code description

نتوبلاسم

## Primary outcomes

### 1

#### Description

The effect of alpha-boic acid on the amount of saliva in cancer patients undergoing head and neck radiotherapy

#### Timepoint

Before starting radiotherapy and 2-6-8-12 weeks after radiotherapy

#### Method of measurement

Collection of unstimulated saliva in the Falcon tube within 5 minutes

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients using 300 mg alpha-phaliboic acid capsules under the name of Elbik by Raha

Pharmaceutical Company twice a day for three months, and the control group of patients using placebo with the same form and the same way of administration as the original drug

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Tajrish Martyrs Hospital, Department of Radio-oncology

**Full name of responsible person**

HEIDARI MASSUME

**Street address**

میدان تجریش بیمارستان شهدای تجریش کد پستی 1989934148

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pr-shohada@sbmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

FARID Akhavan GHOLAM REZA

**Street address**

Isfahan - km 7 of Shiraz Road - Safeh Industrial Town - Unit 11

**City**

ESFAHAN

**Province**

Isfahan

**Postal code**

81791-35148

**Phone**

+98 31 3654 0859

**Email**

marketing@rahapharm.com

**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**

Industry

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Heidari Massume

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

oromaxillofacial medicine

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**Contact**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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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**

no more information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**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**

We do not publish data

**When the data will become available and for how long**

After defending the thesis and exposition of the article,  
we provide access

**To whom data/document is available**

Not applicable

**Under which criteria data/document could be used**

Not applicable

**From where data/document is obtainable**

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

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

Not applicable

**Comments**