

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2019

Effect of vitamin E on prevention of oral mucositis in patients undergoing head and neck radiotherapy

Protocol summary

Study aim

Evaluation of the effect of using and not using (Control) of vitamin E on the oral mucositis caused by head and neck radiotherapy at radiotherapy ward of Imam Hussein hospital in 2017-2018

Design

clinical trial with control group, with parallel groups, Double blind, stratified randomized, Sample size: 24

Settings and conduct

The study is a clinical trial that all patients who have radiotherapy indications who referred to Imam Hussein hospital's radiotherapy department at the time of the study and who have expressed their written consent to participate in the study. Patients were randomly assigned to case group, which received 200mg oral vitamin E daily and placebo for control group. Patients are monitored during the use of drugs and after several days, a clinical examination will be performed, the patient and the weekly assessor are unaware of the patient's treatment group. For examination oral cavity is divided into 12 hypothetical areas by the Epstein method and his partners and according to the second version of the CTC-NCI scoring, the intensity of mucositis in each area is scored. Then the average value will be obtained. Patients are examined on a weekly basis for 8 weeks from the start of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Patients with radiotherapy indication of at least 50Gy throughout the entire study and at least two areas in the field of radiotherapy from the mouth involved in the tumor. Exclusion criteria are: oral mucositis, diabetes, candidiasis, do not consume tobacco.

Intervention groups

Intervention group: Vitamin E, control group: Placebo

Main outcome variables

Oral mucositis severity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT20180924041119N1**
Registration date: **2018-10-12, 1397/07/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-12, 1397/07/20**

Update count: **0**

Registration date

2018-10-12, 1397/07/20

Registrant information

Name

Arash Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 0925

Email address

elhp@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin E on prevention of oral mucositis in patients undergoing head and neck radiotherapy

Public title

Effect of vitamin E on Prevention of oral inflammation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have a radiotherapy indication of at least 50Gy throughout the study At least two areas in the radiotherapy field from mouth are involved the tumor

Exclusion criteria:

Patients with diabetes Patients with Candidiasis Patients who use tobacco.

Age

To 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are stratified randomized, so that patients who are included in the study are stratified in terms of age above 50 years of age and of possible chemotherapy at the same time as radiotherapy. Randomization was performed by a 4-block stratified technique.

Blinding (investigator's opinion)

Double blinded

Blinding description

Although patients are aware of the study and are given written consent, they are unaware of the fact that the medication is effective or placebo. Also, the controlling person, who examines patients for follow up from the beginning to the end of the study at the hospital, is unaware of which patient is in what group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Azad Universty of Tehran Medical Sciences

Street address

No. 4, Neyestan 10, Pasdaran st, Tehran

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2018-06-02, 1397/03/12

Ethics committee reference number

IR.IAU.TMU.REC.1397.026

Health conditions studied

1

Description of health condition studied

Prevention of oral mucositis caused by head and neck radiotherapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of Vitamin E Preventional Effects on Oral Mucositis

Timepoint

At the beginning of the study (before the intervention) and 7, 14, 21, 28, 35, 42, 49 and 56 days after the start of taking the drug and placebo

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vitamin E, a daily dose of 200 mg, manufactured by the Dana Pharmaceutical Company, it is prescribed from first session of radiotherapy to 8 weeks.

Category

Prevention

2

Description

Control group: Placebo, in the same color and size as the original drug, was produced by the Dana Company and it has used in the same manner.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Elham Hosseinpour

Street address

Madani St, Imam Hossein Square, Nezam Abad

City

Tehran

Province
Tehran
Postal code
1916893813
Phone
+98 21 7343 2338
Fax
+98 21 7755 7069
Email
info@ehmc.ir
Web page address
<http://ehmc.sbmu.ac.ir>

Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No.9, Neyestan 9, Pasdaran st
City
Tehran
Province
Tehran
Postal code
1958517511
Phone
+98 21 2258 0925
Email
drarashazizi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Majid
Street address
Khaghani St, Shariati St,
City
Tehran
Province
Tehran
Postal code
1916893813
Phone
+98 21 2200 6660
Email
pezeshkitehran.8@gmail.com
Web page address
<http://iautmu.ac.ir>

Grant name

Grant code / Reference number

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

No

Title of funding source

Azad University of Tehran 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
Islamic Azad University
Full name of responsible person
Arash Azizi

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Arash Azizi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No.9, Neyestan 9, Pasdaran st
City
Tehran
Province
Tehran
Postal code
1958517511
Phone
+98 22580925
Email
drarashazizi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Elham Hosseinpoor
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
No.9, Neyestan 9, Pasdaran st
City

Tehran
Province
 Tehran
Postal code
 1958517511
Phone
 +98 21 2248 2251
Email
 ehp1390@gmail.com

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

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Will not be published

When the data will become available and for how long

None

To whom data/document is available

No one

Under which criteria data/document could be used

Unauthorized

From where data/document is obtainable

-

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

-

Comments
