Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative effects of Vitamin E, Hyaloronic acid and Triamcinolone combination versus Triamcinolone alone on oral mucositis induced by radiotherapy

Protocol summary

Study aim

Comparison between vitamin E, hyaluronic acid and triamcinolone with triamcinolone mouthwash in radiotherapy induced mucositis

Design

This study was a triple blind clinical trial with the aim of comparing the combination of vitamin E, hyaluronic acid and triamcinolone with triamcinolone mouthwash, and to collect data from a clinical examination and medical records of patients (including: Type of cancer, total radiation dose and number of treatment sessions).

Settings and conduct

Patients with any type of malignant neoplasm referring to Imam Khomeini Hospital, Tehran University of Medical Sciences, who are undergoing radiotherapy in an outpatient setting, will be included in this study. After diagnosis of Grade 3 and 4 oral mucositis, taking into account the criteria for entering and leaving the study.

Participants/Inclusion and exclusion criteria

Patient entry requirements include: Patients with (at least 18 years of age) (no maximum age limit, Patients with definite cervical cancer diagnosis according to histopathologic examination, Observe oral hygiene in a way that does not prevent the degree of mucositis severity, The patient has the ability to use mouthwash, Grade 3 and 4 oral mucositis according to WHO grade, No history of susceptibility to the drugs studied (so that patients are asked about drug sensitivities prior to entering the study and if they have not a history of hypersensitivity, they are included in the study, Signing consent form inform.ed

Intervention groups

Patients with any type of malignant neoplasm referring to Imam Khomeini Hospital, Tehran University of Medical Sciences, who are undergoing radiotherapy in an outpatient setting, will be included in this study.

Main outcome variables

Failure to tolerate mouthwash is reported by patients, and if the number reaches a significant number of people, the study will be stopped.

General information

Reason for update

Some dates need updating. Due to the termination of the trial, the exact termination date can be recorded. Also, the expected start and the exact date of starting the trial were postponed until the end of the IRCT registration process.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190428043407N1**
Registration date: **2019-07-20, 1398/04/29**
Registration timing: **prospective**

Last update: **2020-10-03, 1399/07/12**
Update count: **1**

Registration date

2019-07-20, 1398/04/29

Registrant information

Name

mona pourpasha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8891 2091

Email address

pourpasha.mona@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

2019-07-23, 1398/05/01

Actual recruitment end date

2019-12-06, 1398/09/15

Trial completion date

2020-01-06, 1398/10/16

Scientific title

Comparative effects of Vitamin E, Hyaloronic acid and Triamcinolone combination versus Triamcinolone alone on oral mucositis induced by radiotherapy

Public title

Comparative effects of Vitamin E, Hyaloronic acid and Triamcinolone combination versus Triamcinolone alone on oral mucositis induced by radiotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient entry requirements include: Patients with (at least 18 years of age) (no maximum age limit, Patients with definite cervical cancer diagnosis according to histopathologic examination, Observe oral hygiene in a way that does not prevent the degree of mucositis severity, The patient has the ability to use mouthwash, Grade 3 and 4 oral mucositis according to WHO grade, No history of susceptibility to the drugs studied (so that patients are asked about drug sensitivities prior to entering the study and if they have not a history of hypersensitivity, they are included in the study, Signing consent form informed

Exclusion criteria:

Patient withdrawal criteria from the study include: Pregnant women who recently used (3 weeks) vitamin E and other supplemental antioxidants, Patients with other active oral lesions (such as major asthma), History of alcohol use, Drugs - Performing previous radiotherapy treatments and current chemotherapy treatments and bone marrow transplants with clinical, neurological, endocrine and other systemic diseases. Karnofsky performance status scale less than 60 (Patients in need of admission)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **58**

Actual sample size reached: **59**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method will be based on the Balanced Block randomization method using the Microsoft Excel software. The number and size of blocks are determined by the individual. After the random allocation list has been obtained, on the mouthwash package (containing 4 glasses) and on the glass the consecutive numbers (from 1 to the final sample size) are written. A random assignment list is maintained in two versions and in two different locations by the person who generates the random allocation list until the data is analyzed. Randomization is done by an individual who is independent of the results and is not the beneficiary. The organizer of the plan is responsible for evaluating patients and forcing them to study and allocate interventions to them.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the investigator (executor) responsible for administering interventions and the outcome of the outcome, the patients and the statistical analyzer of which patient are in the intervention group and which control group is not known, and only patient records recorded during the successive weeks 1 to 4 , In the form of groups A and B is provided to the analyzer (Triple Blind).

Placebo

Not used

Assignment

Other

Other design features

The data required for the study are recorded in the forms provided by the moderator. Part of the information will be obtained by asking the patient and examining his case and the other part by the investigator's examination of the patient. Details are listed in the evaluation section of the study outcomes.Regular fast-tracking and daily follow-up through telephone calls increase patient adherence to proper protocol (oral maturation) and more confidence in the outcome. Failure to comply with medical orders of less than 70% and non-compliance with a visit of less than 70% will be considered as a deviation from the protocol. Data will be entered in the SPSS software without name and based on the code of the study. These data are provided to the statistical analyzer after determining whether each person belongs to one of the two groups without knowledge of the intervention or comparison of each group (by third party). * The method of analysis of the basic statistics related to The patient and the characteristics of the disease as well as the variables affecting the outcome of the study (probable confounders) are divided into two groups of study, to evaluate the accuracy of random allocation and the ability to compare the two groups.The percentage of mucositis intensity decreases qualitatively in two groups and will be compared with Chi-square statistical analysis. The severity of pain will be evaluated quantitatively after examining the data distribution with independent t-test or Mann-Whitney test. The frequency

of complications in each group is reported by the Chi-square test (or Fisher test). The statistical significance is considered to be less than 0.05. More analyzes are performed after analyzing the primary and secondary consequences for the subgroup analyzes Will decide

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of dentistry- Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, High School of Dentistry, not reaching the exit of Hakim East, next to Atomic Energy Organization, End of North Worker Street

City
Tehran

Province
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Postal code
1439955991

Approval date
2018-09-23, 1397/07/01

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1398.043

Health conditions studied

1

Description of health condition studied
Oral mucositis induced by radiotherapy

ICD-10 code
K12.33

ICD-10 code description
Oral mucositis (ulcerative) due to radiation

Primary outcomes

1

Description
PAIN

Timepoint
weeks1,2,3,4

Method of measurement
Numerical pain scale

2

Description
The rate of improvement in the severity of oral lesions

Timepoint
possible change of oral mucositis grade from 3 and 4 to steady levels

Method of measurement
WHO Grading

3

Description
Type of prescription

Timepoint
weeks 1,2,3,4

Method of measurement
Based on the study method

4

Description
period of time

Timepoint
Date of referral of patients in weeks 1, 2, 3 and4

Method of measurement
Week 1 and 2, 3, and 4 Treatments

5

Description
gender

Timepoint
Date of referral of patients

Method of measurement
observation

6

Description
Age

Timepoint
Date of referral of patients

Method of measurement
Ask the patient

Secondary outcomes

1

Description
Lack of the mouth wash tolerance is noted by patients and the study will be stopped if there are significant numbers of these people.

Timepoint
weeks 1,2,3,4

Method of measurement
ask the patient

Intervention groups

1

Description
Intervention group: Treatment of patients with oral mucositis induced by head and neck radiotherapy by mouthwash contains of vit E , hyaluronic acid and triamcinolone

Category
Treatment - Drugs

2

Description
Control group: Treatment of patients with oral mucositis induced by head and neck radiotherapy by triamcinolone mouthwsh
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
FARZANEH AGHAHOSSEINI
Street address
BAQERKHAN Street, West Chamran Highway, Tehran Province, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
FARZANEH AGHAHOSSEINI
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dentistry@tums.ac.ir
Web page address
http://dentistry.tums.ac.ir
Grant name
Faculty of Education
Grant code / Reference number
98-01-70-38775
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
FARZANEH AGHAHOSSEINI
Position
Full Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Position
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Person responsible for updating data

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Web page address
https://dentistry.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After the data collection and completion of the study, the dissertation and the article will be displayed.

When the data will become available and for how long
Until the completion of the data collection

To whom data/document is available
The organizer collects the information plan as blind and analyzer analyses it blind and then By the third person, the results of the study will be specified.

Under which criteria data/document could be used
It will be acceceble in the form of a paper for use and general application.

From where data/document is obtainable
full professor.Dr. Farzaneh aghahoseini

What processes are involved for a request to access data/document
Search in the motor searches

Comments
All of the above will be available upon completion of the research work