Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Effectiveness of Green tea mouth rinse on radiation-induced mucositis in patients with head and neck cancer:A Randomized clinical trial

Protocol summary

Summary

Fifty patients with head and neck cancer who recieve reffer to Cancer Institute of Imam Khomeini Hospital will divide into two groups by balanced block randomization method and will receive green tea mouthwash (intervention group) and normal saline mouthwash (control group). During 8week period of radiotherapy, all the patients will be examined once a week and any erythema, ulcers and mouth burns (VAS) will be recorded by a blind examiner. Finally results of both groups will be compared to each other and will be analyzed statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090914606N1**
Registration date: **2014-04-27, 1393/02/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-27, 1393/02/07

Registrant information

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Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-02-18, 1391/11/30

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Green tea mouth rinse on radiation-induced mucositis in patients with head and neck cancer:A Randomized clinical trial

Public title

Effectiveness of Green tea mouth rinse on radiation-induced mucositis in patients with head and neck cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients older than 18 years old; patients that are diagnosed with the head and neck cancer; minimum dose of radiation therapy must be 50Gy to induce mucositis; patients who are able to use mouthwash before radiotherapy session; patients sign informed consent; at least 50% of the oral cavity area should be under radiation fields; having an ideal oral hygiene; absence of active infection in the oral cavity such as HSV, candida and aphthous ulcers. Exclusion criteria: patients currently suffering from any kind of oral diseases, e.g. active oral infection, ulcer, etc.; patients receiving chemotherapy combined with radiotherapy patients that are not able to use mouthwash; patients who have a broad extent of the lesions and grade IV mucositis; patients who use local anesthetic in the study;

patients who are not willing to leave their unsafe habits such as smoking, alcohol, spicy and acidic foods; patients with a history of allergy to green tea; patients with lesions in the oral cavity area; patients who recently have used prostaglandin inhibitors, vitamin E and antioxidant supplements; lack of cooperation at every stage of project.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Qods st., Keshavarz boulevard

City
Tehran

Postal code

Approval date
2014-02-18, 1392/11/29

Ethics committee reference number
92-03-69-21298-106779

Health conditions studied

1

Description of health condition studied
Radiation induced oral mucositis

ICD-10 code
K12.3

ICD-10 code description
Mucositis(oral) (oropharyngeal): NOS

Primary outcomes

1

Description
type of mouthwash for treatment

Timepoint
after the termination of study

Method of measurement
revealing the mouth wash anyone was receiving after the end of study

2

Description
sex

Timepoint
before the beginning of study

Method of measurement
observation

3

Description
Weight

Timepoint
At the beginning and end of radiotherapy

Method of measurement
Scaler

4

Description
Received radiation dose

Timepoint
The total dose received during the meetings

Method of measurement
Grey

5

Description
age

Timepoint
at the beginning of study

Method of measurement
year

6

Description
Name of cancer

Timepoint
Before the beginning of study

Method of measurement
Pathology report

7

Description
Cancer location

Timepoint
Before the beginning of study

Method of measurement
Medical records

Secondary outcomes

1

Description
Pain and soreness
Timepoint
Every week
Method of measurement
Visual analogue scale

2

Description
Mucositis grading
Timepoint
Every week
Method of measurement
WHO grading(0-4)

Intervention groups

1

Description
Green tea mouth rinse with 3%concentration in the intervention group for the prevention of radiation induced mucositis and 0.9% saline were used as controls. These interventions will continue for 8 weeks.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Cancer Institute of Imam Khomeyni Hospital
Full name of responsible person
Soheila Manifar
Street address
Imam Khomeyni hospital, Keshavarz Boulevard
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Masoud Yunesian
Street address
Vice chancellor for research, Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty