

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 receive refer 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

Name

Shiva Shirazian

Name of organization / entity

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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

Tehran University of Medical Sciences

Full name of responsible person

Azeen Rashtiyani

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Student of dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

Shiva Shirazian

Position

Assistant professor

Other areas of specialty/work

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Position

Assistant professor of oral medicine at school of dentistry

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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