

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparing the effect of two mouth washing protocols in the prevention of head and neck radiotherapy -induced stomatitis

Protocol summary

Summary

The Purpose of this study is to compare two mouthwashes in the prevention of head and neck radiotherapy- induced stomatitis. This study is a single-blind randomized controlled trial. Inclusion criteria: diagnosis of head and neck cancer, age of 18-60 years, not to treat with steroid, avoiding tobacco, alcohol, smoking and opiate substances. Exclusion criteria: being allergic to the mouth wash solutions, T>38/5c. Subjects are randomly assigned to 3 groups (group1=honey, group2=chamomile, group3= water mouthwashes). Both the honey and chamomile oral rinse are applied using the same technique with 60 (s) contact times. The examination will be performed with WHO grading scale of 0-4.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902053788N1**

Registration date: **2010-09-27, 1389/07/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-27, 1389/07/05

Registrant information

Name

Shiva Sadat Bassampour

Name of organization / entity

Tehran University of Medical Scinces

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Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

bassampour@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-04-19, 1389/01/30

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of two mouth washing protocols in the prevention of head and neck radiotherapy -induced stomatitis

Public title

cancer & mouth washing

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of head and neck cancer; age of 18-60 years; not to treat with steroid; avoiding tobacco, alcohol, smoking and opiate substances; external beam radiotherapy with dose 180-200 CGY Daily. Exclusion Criteria: not to rinse 5 time with mouth washing; being allergic to the mouth washing solutions; T>38/5c; nausea and vomiting; certain systemic condition such as diabetes, defect in the immune system, renal disease, liver disease, GI disease, asthma, allergy; Leucopenia (WBC<4000mm³); Leucocytes (WBC>12000mm³); Thrombocytopenia.

Age

From **12 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Review Committee of Tehran University of Medical Sciences

Street address

Keshavarz BLD, Ghods street, Central building of Tehran University of Medical Sciences, 6th floor

City

Tehran

Postal code**Approval date**

2010-05-20, 1389/02/30

Ethics committee reference number

62/130/89/ص

Health conditions studied**1****Description of health condition studied**

Cancer

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes**1****Description**

Stomatitis

Timepoint

14 days

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 2: Chamomile Mouth washing

Category

Prevention

2**Description**

Control group: Water mouth washing

Category

N/A

3**Description**

Intervention group 1: Honey mouth washing

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Radiotherapy Unit of Shafa Hospital

Full name of responsible person

Shivassadat Bassampour

Street address

Shafa Hospital

City

Kerman

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Abbas Hoshmand Behabadi

Street address

Nosrat ST.Tohid SQ, Faculty of Nursing and Midwifery

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor**

organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, 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

Shivassadat Bassampour

Position

Instructor

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of Medical Science

Full name of responsible person

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Full name of responsible person

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Graduate Student

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Web page address**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