Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Country
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 Commiitee 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 Scinces
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 Scinces
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 Siences
Full name of responsible person
Shivassadat Bassampour
Position
Instructor
Other areas of specialty/work
Street address
Nosrat ST,Tohid Sq, Faculty of Nursing and Midwifery
City
Tehran
Postal code
Phone
+98 21 6690 4252
Fax
Email
bassampour@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Science
Full name of responsible person
Mohammad Hasan Larizadeh
Position
Assistant Professor
Other areas of specialty/work
Street address
Shafa hospital
City
Kerman
Postal code
Phone
+98 34 1223 5011
Fax
Email
larizad_MH@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Siences
Full name of responsible person
Fatemeh Bahram Nezhad
Position
Graduate Student
Other areas of specialty/work
Street address
Nosrat St, Tohid Sq, Faculty of Nursing and Midwifery
City
Tehran
Postal code
Phone
+98 913 397 4856
Fax
Email
bahramnezhad@tums.ac.ir , fatemeh_bahramnezhad@yahoo.com
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