

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of using ice for preventing oral mucositis associated with head and neck radiotherapy

Protocol summary

Summary

Objectives: Mucositis, which usually occurs with chemotherapy and radiotherapy, causes pain, loss of taste, difficulty in eating foods, and subsequently weight loss. Reviewing literature reveals that using ice chips can significantly prevent mucositis during chemotherapy, and the aim of this study is to see the impact of ice chips on mucositis during radiotherapy. Design: 40 patients were divided randomly into 2 groups. Control group patients merely receive ordinary oral care, which consists of soft toothbrush, non-erosive toothpaste, and dental floss. Intervention group patients use ice cubes 5 minutes before and after each radiotherapy session, in addition to ordinary oral care. Setting and conduct: Patients will be examined on 1st, 7th, and 14th day of study, and mucositis will be assessed by both dentists and patients, using questionnaires. Comparison of improvement percentage between two groups will be performed by chi square test, and comparison of mucositis severity between two groups will be performed by kruskal-wallis test. In order to determine the relationship between mucositis and variables such as cancer type, radiation power, intervention type etc logistic regression will be used. Inclusion criteria: patients undergoing radiotherapy in mouth or part of head and neck; at least one salivary gland must be in the field of radiation (more than 3000 Gy). Exclusion criteria: existence of mucositis before starting radiotherapy; any systemic disease or medicine consumption affecting oral cavity. Intervention: patients of this group hold the ice cubes in their mouths for 5 minutes before and after each radiotherapy session, everyday. Main outcome measures (variables): 1. physician judged mucositis: clinical examination by the dentists and filling standardized physician judged mucositis grading forms on 1st, 7th, and 14th days of the study. 2. patient-judged mucositis: interview with patient and filling standardized patient-judged mucositis grading forms on 1st, 7th, and 14th days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107127015N1**

Registration date: **2011-08-28, 1390/06/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-28, 1390/06/06

Registrant information

Name

Amir Reza Ghassemi

Name of organization / entity

Kerman university of medical sciences and health service, dental school

Country

Iran (Islamic Republic of)

Phone

+98 34 1244 3739

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2009-06-01, 1388/03/11

Expected recruitment end date

2010-06-01, 1389/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty
Scientific title
Evaluation of using ice for preventing oral mucositis associated with head and neck radiotherapy
Public title
Evaluation of using ice for preventing oral mucositis associated with head and neck radiotherapy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: persons undergoing radiotherapy in mouth or part of head and neck; at least one salivary gland must be in the field of radiation (more than 3000 Gy) Exclusion criteria: existence of mucositis before starting radiotherapy; any systemic disease or medicine consumption affecting oral cavity
Age
No age limit
Gender
Both
Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: 40
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

<u>1</u>
Ethics committee
Name of ethics committee
ethics committee of Kerman university of medical sciences and health service, research deputy
Street address
Tahmasb abad junction, Shariati St.
City
Kerman
Postal code
Approval date
2007-12-03, 1386/09/12
Ethics committee reference number
k/86/45

Health conditions studied

<u>1</u>
Description of health condition studied
oral mucositis
ICD-10 code
k12
ICD-10 code description
Stomatitis and related lesions

Primary outcomes

<u>1</u>
Description
physician judged mucositis
Timepoint
1st, 7th, and 14th days
Method of measurement
clinical examination by the dentists and filling standardized physician judged mucositis grading forms

<u>2</u>
Description
patient-judged mucositis
Timepoint
1st, 7th, and 14th days
Method of measurement
interview with patient and filling standardized patient-judged mucositis grading forms

Secondary outcomes

empty

Intervention groups

<u>1</u>
Description
using ice cubes in intervention group: patients of this group hold the ice cubes in their mouths for 5 minutes before and after each radiotherapy session everyday.
Category
Prevention

<u>2</u>
Description
standard oral health care: in both groups of intervention and control, toothbrush, toothpaste, and tooth floss was used twice a day.
Category
Prevention

Recruitment centers

<u>1</u>
Recruitment center

Name of recruitment center
Dept. of Oncology, Shafa hospital
Full name of responsible person
Dr. Shahla Kakoei
Street address
Shafa hospital, Shafa blvd, Kerman
City
Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Dr. Reza Malekpour Afshar
Street address
Tahmasb abad junction, Shariati St.
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Kerman

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, Kerman 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
Oral diseases research center
Full name of responsible person
Dr. Amir Reza Ghassemi
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

