Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

a.r_ghassemi_dent@yahoo.com

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

1

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

1

Description of health condition studied
oral mucositis

ICD-10 code
k12

ICD-10 code description
Stomatitis and related lesions

Primary outcomes

1

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

2

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

1

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

2

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

1

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.
City
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
Position
Doctor of dental science (D.D.S)
Other areas of specialty/work
Street address
Oral diseases research center, Kowsar Blvd.
City
Kerman
Postal code
Phone
+98 34 1244 3739
Fax
Email
a.r_ghassemi_dent@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oral diseases research center
Full name of responsible person
Dr. Shahla Kakoei
Position
Doctor of dental science. Specialist of oral biology
Other areas of specialty/work
Street address
Oral diseases research center, Kowsar Blvd
City
Kerman
Postal code
Phone
+98 913 140 8974
Fax
Email
skakoei@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Oral diseases research center
Full name of responsible person
Dr. Amir Reza Ghassemi
Position
Doctor of dental science (D.D.S)
Other areas of specialty/work
Street address
Kowsar Blvd., Oral diseases research center, Kerman
City
Kerman
Postal code
Phone
+98 34 1244 3739
Fax
Email
a.r_ghassemi_dent@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*