

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

The effect of folic acid mouthwash solution in prevention of head and neck radiotherapy -induced stomatitis

Protocol summary

Study aim

Determining the Effect of Folic Acid Mouthwash on Prevention of Stomatitis in Patients Under Head and Neck Radiotherapy. _____

Design

Clinical trials with control and intervention group, with parallel and randomized groups.

Settings and conduct

This study was conducted in the Radiotherapy section of Imam Reza Hospital in Mashhad

Participants/Inclusion and exclusion criteria

Satisfaction to participate in the study, lack of immunosuppression and absence of leukocyte and leukocytosis, aged 18 to 60 years, lack of underlying disease (diabetes, kidney disease, liver disease), oral mucosa, and mucosal lesions, The daily intake of external radiation therapy with a dose of 200-180(cGy) for one hour, does not have a history of smoking in a recent month; the lack of simultaneous use of chemotherapy with radiation therapy during the study, lack of sedative, non-use of mouthwash and other medication for Oral ulceration during research, lack of artificial teeth, death, any complications that occur during the study and not able to participate in the study, fever above 38.3 ° C, lack of willingness to continue cooperation in the study, more Do not get 20% mouthwashes during the study

Intervention groups

Combined folic acid solution containing folic acid = 100 mg, NaHCO₃=38 mg, propyl parahydroxybenzoate = 25 mg, methyl parahydroxy benzoate = 50 mg, conc peppermint water= 2 ml, distilled water = Up to 100 ml volume) for 14 days at two times in the morning and at night for one minute and then routine mouthwash (magic) with a 15 minute interval and control group 2 times with a distance of more than 15 minutes in two turns In the morning and at night, routine mouthwash is used.

Main outcome variables

Severity of stomatitis, Severity of pain caused by stomatitis, Incidence of oral ulcers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180526039847N1**

Registration date: **2019-06-19, 1398/03/29**

Registration timing: **retrospective**

Last update: **2019-06-19, 1398/03/29**

Update count: **0**

Registration date

2019-06-19, 1398/03/29

Registrant information

Name

Zahra Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

gholamiz932@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

2018-08-05, 1397/05/14

Actual recruitment end date

2019-03-05, 1397/12/14

Trial completion date

2019-03-05, 1397/12/14

Scientific title

The effect of folic acid mouthwash solution in prevention of head and neck radiotherapy –induced stomatitis

Public title

The Effect of Folic Acid Mouthwash on Stomatitis Caused by Head and Neck radiotherapy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfied to participate in the study The mucous membrane is healthy and free from mucosal lesions and oral and dental problems Age of 18 to 60 years Receive external radiotherapy and radiation at a dose of 180 CGy per day for one hour During the study, do not use any mouthwash and other medication for oral ulcers Not having dentures

Exclusion criteria:

Having immunodeficiency disease and having leukopenia and leukocytosis Having underlying illness (diabetes, kidney disease, liver disease) There is a history of tobacco use, including smoking, hookah, and narcotics in the last month Chemotherapy drugs receive simultaneous radiotherapy during the study Receives sedative During the study, do not use any mouthwash and other medication for oral ulcers

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a random number table with 0-9 assignment to two groups of intervention and control, then on the random numbers table, set the starting point to blinded and specify the sequences of the sequence of the group on the random numbers of the starting point with a blind eye And sequences of sequence numbers of the intervention and control group are determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

Mouthwashes of folic acid and magic in similar containers and dividing the dishes into two groups (a, b) and delivering mouthwash to the patients by clinical care will not be known to the researcher in the relationship to the

type of mouthwash.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Crossroad of the Doctora., Mashhad city

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2017-11-24, 1396/09/03

Ethics committee reference number

IR.MUMS.REC.1396.292

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

Stomatitis caused by radiotherapy for head and neck

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis (ulcerative)

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

The incidence of stomatitis

Timepoint

Before the start of the first and seventh and fourteenth days of Radiotherapy, the incidence of stomatitis, pain, mouth ulcers in patients' records.

Method of measurement

The World Health Organization standard tool for measuring stomatitis, pain visual analog scale (Visual Analogue Scale), measuring instruments sores (oral mucositis assessment scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Combined folic acid solution containing (folic acid = 100 mg, NaHCO₃=38 mg, propyl parahydroxybenzoate = 25 mg, methyl parahydroxy benzoate = 50 mg, conc peppermint water= 2 ml, distilled water = Up to 100 ml volume)(This mucosal formulation has been used in several cases for gingivitis, which was developed and used by the pharmacist's professor at the Pharmacy Lab of Mashhad University of Medical Sciences for this study) and each time 5 cc for 14 days in Garnish two minutes in the morning and at night and then routine mouthwash (Magic) at 15 minutes intervals. and they do not eat anything until 15 minutes later.

Category

Prevention

2

Description

Control group: The routine oral mucosal control group (magic) with the combination (Aluminum MGS syrup, diphenhydramine syrup, lidocaine ampoules, dexamethasone ampoules, nystatin drops) 2 times more than 15 minutes for 14 days, twice a day for one minutes and they do not eat anything until 15 minutes later. The mouths of patients are examined on the first, seventh and fourteenth days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Educational Research Center

Full name of responsible person

Seyyed Mousa Mahdizadeh

Street address

Imam Reza Square Imam Reza Educational Research Center

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3859 1511

Email

MahdizadehM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

University of Mashhad., next to Hivizadeh Cinema., Mashhad University of Medical Sciences., Deputy of Research & Technology University

City

Mashhad

Province

Razavi Khorasan

Postal code

91775-1365

Phone

+98 51 3882 3255

Fax

+98 51 1882 3251

Email

Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

70

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Mousa Mahdizadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery of Mashhad Crossroad of the Doctora., Mashhad city

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Phone

+98 51 3859 1511

Email

MahdizadehM@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Mousa Mahdizadeh

Position

Faculty of Nursing and Midwifery, Mashhad

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Crossroad of the Doctora., Mashhad city

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3859 1511

Email

MahdizadehM@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

zahra Gholami

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Crossroad of the Doctora., Mashhad city

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3601 7651

Email

Gholamiz932@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only the original outcome information

When the data will become available and for how long

Starting the access period from 1399

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Analysis of delivered data is allowed

From where data/document is obtainable

Zahra gholami Gholamiz932@mums.ac.ir

What processes are involved for a request to access data/document

In less than one month, information is provided to the applicant by email.

Comments