

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparision of the effect of probiotics mouthwash and normal saline in the treatment of radiotherapy induced mucositis

Protocol summary

Study aim

The practical purpose of this study was to introduce probiotic mouthwash as one of the effective treatments in oral mucositis ulcers .

Design

Randomized clinical trial with parallel groups, double-blind, phase 2 on 64 patients, Excel software rand function was used for randomization

Settings and conduct

In both groups, in addition to the usual treatment of mucositis, probiotic and normal saline mouthwash is started 1 day before the start of radiotherapy. The patient gargles mouthwash three times a day for 3 minutes. The patient and the distributor of mouthwash do not know the type of mouthwash used. Clinical care is provided at Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

all patients needed head and neck radiotherapy at imam khomeini hospital are eligible for the study.

Intervention groups

During radiotherapy, every 3 days for 6 weeks, patients are examined for mucositis by an examination by Dr specialist in oral medicine, and the patient's mucosal grade is determined by a clinical examination by Dr specialist in oral medicine

Main outcome variables

The sampling process will take time and the study will be long. The main expected outcome is the positive effect of probiotic mouthwash on patients' oral mucosa.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201106049288N1**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **prospective**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Zahra Mofazzal jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2249 0860

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the effect of probiotics mouthwash and normal saline in the treatment of radiotherapy induced mucositis

Public title

Effect of probiotics mouthwash and normal saline in treatment of mucositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

all patients needed head and neck radiotherapy at imam khomeini hospital .

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method is used. For randomization, randomly selected pre-radiotherapy use is selected for inclusion in the study. The first step in performing a random process is to create a random sequence. The second step after creating a random sequence is sequencing generating technology (property privatization acquisition). The purpose of these steps is to prevent any predictions of future allocation by drug sales and distribution companies. Both groups compete with each other using age and gender, and the age of the people in the case group is controlled by the average age of the people in the control group, and thus matching between the two groups takes place.

Blinding (investigator's opinion)

Double blinded

Blinding description

In addition to the patient, the person giving the mouthwash to the patient does not know 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 the School of Dentistry, Tehran University of Medical Sciences

Street address

Khani Abad No - Shahid Zolfi St. (Mahan) - Opposite Shariati Park - School of Dentistry

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-12-19, 1399/09/29

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1399.176

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

Radiotherapy-induced oral mucositis

ICD-10 code

K00-K14

ICD-10 code description

بیماریهای حفره دهانی، غددبزاقی و فک ها

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

The effect of mouthwash on mucositis

Timepoint

Once every 3 days for 6 weeks

Method of measurement

Mucosite grading

Secondary outcomes

empty

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

Intervention group: Probiotic mouthwash is used to prepare probiotic mouthwash from Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus salivarius, Lactobacillus ruteri, Bifidobacterium lactobacillus, Bactidobacterium lactobacillus, The combination of bacteria is prepared in powder form and is provided to the therapist and the patient as a pre-prepared solution.

Category

Treatment - Drugs

2**Description**

Intervention group: To prepare normal saline mouthwash from Tween 80 (500 mg), 5 (Avicel g) and xanthan (2 g), methyl paraben (8.1 g), propyl paraben (200 mg), disodium hydrogen phosphate (2 g), sodium dihydrogen phosphate (3 g) and distilled water are used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان امام خمینی

Full name of responsible person

دکتر سهیلا مانی فر

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra mofazzal jahromi

Position

Dental student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available