Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Ḍr 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)

Phone
+98 21 2249 0860

Email address
zahramofazzal@gmail.com

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

Street address
بزرگراه چمران، خیابان باقرخان، انتهای بلوار کشاور ، مجتمع بیمارستان امام خ

City
تهران

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6119 0000

Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
دکتر مریم کوپایی

Street address
خانی آباد نو - خیابان شهید زلفی(ماهان) - روبروی پارک شریعتی - دانشکده دندانپزشکی

City
تهران

Province
Tehran

Postal code
1417653761

Phone
+98 21 5585 1151

Fax
+98 21 5585 1141

Email
dentistyic@tums.ac.ir

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

Street address
Army Highway, Shahid Mahallati Town, Phase 3, Neighborhood 6, Noor 1st St., Yas 3 Block, Unit 5

City
تهران

Province
Tehran

Postal code
1955737158

Phone
+98 21 2249 0860

Email
zahramofazzal@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Maryam koopaie

Position
DDS.MS. Medicine and oral maxillofacial

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
End of Ashrafi Esfahani, Eghbalpour St., 17th East Alley, No. 15, Unit 4

City
Tehran

Province
Tehran

Postal code
۱۴۷۷۷۸۶۴۱۴

Phone
+98 21 4483 7445

Email
m-koopaie@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zahra mofazzal jahrromi
Position
Dental student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Army Highway, Shahid Mahallati Town, Phase 3, Neighborhood 6, Noor 1st St., Yas 3 Block, Unit 5
City
Tehran
Province
Tehran
Postal code
1955737158
Phone
+98 21 2249 0860
Email
zahramofazzal@gmail.com

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