Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Aug 2026

Comparing of toll like receptor 2 salivary level in head and neck radiotherapy patients with and without probiotic treatment

Protocol summary

Study aim
Comparison of the mean salivary level of Toll like receptor 2 between the two groups with and without probiotics

Design
The clinical trial will have a control group, with parallel groups, three blinded, randomized, phase 3 on 50 patients randomly and by the method of randomized permutation blocks with variable size of variable block 4 and 6 .

Settings and conduct
The clinical efficacy study is conducted in the Department of Cancer Institute of Imam Khomeini Hospital in a three-way blinded manner (patient, evaluator and statistical analyst) by receiving the saliva of patients and checking the level of TLR2 in two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with oral squamous cell cancer referred to the Imam Khimni Hospital Cancer Institute who were diagnosed and operated on the basis of histopathology and are scheduled to undergo IMRT; Patients aged 18 years and older. Exclusion criteria: Lack of written informed consent to participate in the study; Suffering from systemic diseases such as rheumatoid arthritis/hypertension/leukemia/systemic lupus erythromatous and other types of systemic diseases; Having another malignancy and being treated for it; Patients who have already received chemotherapy or are undergoing chemotherapy; Pregnant and lactating women.

Intervention groups
Control group: placebo group. Intervention group: Probiotic mouthwash group.

Main outcome variables
The expression level of Toll like receptor 2

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230624058564N1**
Registration date: **2023-08-06, 1402/05/15**
Registration timing: **prospective**

Last update: **2023-08-06, 1402/05/15**
Update count: **0**

Registration date
2023-08-06, 1402/05/15

Registrant information

Name
Sahar Vaziri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2615 9477

Email address
saharvaziri44@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-21, 1402/05/30

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing of toll like receptor 2 salivary level in head and neck radiotherapy patients with and without probiotic treatment

Public title
Comparing of toll like receptor 2 salivary level in head and neck radiotherapy patients with and without probiotic treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with head and neck cancer referred to the Imam Khomeini Hospital Cancer Institute who were diagnosed and operated on the basis of histopathology and are scheduled to undergo IMRT Patients aged 18 years and older

Exclusion criteria:
1. Lack of written informed consent to participate in the study 2. Suffering from systemic diseases such as rheumatoid arthritis/hypertension/leukemia/systemic lupus erythromatous and other types of systemic diseases. 3.Having another malignancy and being treated for it 4. Patients who have already received chemotherapy or are undergoing chemotherapy. 5. Pregnant and lactating women

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning drugs to patients will be randomly and by random permutation blocks with a block size of 4 and 6 changes. The random list will be obtained manually and using the tables in the book "Design and Analysis of Clinical Trials" which is provided under its reference. The random list preparation method will be as follows: In the present study, placebo and probiotic groups (2 groups) were consideredPatients enter the study in order and they are assigned a code according to the order of their entry (codes 1 to 44). To make the first block (for example: a block of size 4), the numbers 1, 2, 3, and 4 are randomized. For example, the order of randomization is 2, 4, 1 and 3, in this case, in the probiotic group, patients with codes 2 and 4 and in the placebo group, patients with codes 1 and 3 are included. To make the second block (for example: a block of size 6), the numbers 5, 6, 7, 8, 9 and 10 are randomized. Suppose the order of randomization is 10, 7, 9, 5, 6 and 8. In this case, in the probiotic group, patients with codes 10, 7, 9 and in the placebo group, patients with codes 5, 6, and 8 are included in the study. This work will be done until all the blocks are obtained and the sample size of 22 people in each group is reachedIn order to conceal the allocation, sealed envelopes are prepared, the contents of which are not known, and envelope numbers 1 to 44 are inserted. Inside each envelope, based on the list of random numbers, the name of the group to which the person will be assigned is mentioned. It should be noted that this step will be performed by a person who has no role in the evaluation of patients. (1) 1. Fleiss JL. Design and analysis of clinical experiments: John Wiley & Sons; 2011.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study will be done in a three-way blind. In this research, the patient, the evaluator (the person who measures the results of the study) and the statistical analyst (dissertation statistics consultant) will be uninformed (blind) of the groups under study. The two drugs used in this research are mouthwashes of the same color with the same smell and temperature, which are placed in containers with the same weight and the same appearance, and are numbered by the pharmacist based on a random list. Each patient who enters the study (in the order of patients' entry) is assigned a code and receives the medicine corresponding to that code. Neither the evaluating dentist nor the patient will know the contents of the packages (because each package has a code and only the manufacturer of the drugs will know the contents of the packages). And the nature of the drugs will be revealed after analyzing the results.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research Faculty of Dentistry - Tehran University of Medical Sciences

Street address
Farmanieh, Dibaji Shamli Street, Mahmoud Noorian Street, Shahnaz Street, Safa Street, 20 Unit 4

City
Tehran

Province
Tehran

Postal code
1953643815

Approval date
2022-09-04, 1401/06/13

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1401.084

Health conditions studied

1

Description of health condition studied
Head And Neck Cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Toll like receptor 2
Timepoint
The expression level of Toll like receptor 2 is measured by ELISA method at two basic times (once before the start of treatment and once after the completion of radiotherapy treatment) and after the completion of radiotherapy treatment.
Method of measurement
Toll like receptor 2 is performed through ELISA test kit and saliva test

Secondary outcomes

1

Description
The percentage of people who get grade 2 oral mucositis.
Timepoint
They will be checked for oral mucositis once every three days, and the condition of oral mucositis will be recorded and if it is, its grade will be recorded.
Method of measurement
Based on the amount of oral ulcers, it is examined and recorded by a specialist in oral and dental diseases.

Intervention groups

1

Description
Intervention group:Intervention group: This group will be given the nutritional counseling that was given to the control group (placebo) for prevention, and in addition, probiotic mouthwash will be prescribed. The way to prepare probiotic mouthwash is to take 3 grams of Femilact powder (femilact zist Takhmir Iran), which contains the composition of probiotic powder containing colony-forming u unit 13.5 x 1010 Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus salivarius, Lactobacillus roteri, Bifidobacterium lactis, Bifidobacterium longum and Bifidobacterium debifidom are dissolved in 70 ml of normal saline.They are kept in 70 ml bottles at room temperature and have been checked for physical stability during two months and no changes in their color, smell and aroma have been made. The patient is asked to use the mouthwash three times a day and keep the mouthwash in his mouth for at least 1 to 2 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Cancer Institute Center
Full name of responsible person
Soheila Manifar
Street address
Imam Khomeini Hospital, at the end of Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
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
Fateme Dibaji
Street address
Nawab Highway, the beginning of Khani Abad No, Mahan St. (Shaheed Zulfi), in front of Shariati Park, Faculty of Dentistry, International Campus
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6739 5115
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
Sahar Vaziri
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Tehran Farmanieh, Dibaji Shamli Street, Mahmoud Noorian Street, Shahnaz Street, Safa Street, 20 Unit 4
City
Tehran
Province
Tehran
Postal code
1953643815
Phone
+98 21 2615 9477
Email
saharvaziri44@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sahar Vaziri
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Tehran Farmanieh, Dibaji Shamli Street, Mahmoud Noorian Street, Shahnaz Street, Safa Street, 20 Unit 4
City
Tehran
Province
Tehran
Postal code
1953643815
Phone
+98 21 2615 9477
Email
saharvaziri44@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sahar Vaziri
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No 20 Safa Alley, Shahnaz Alley ,Mahmod nourian Ave,Dibaji shomali Ave ,Tehran Town
City
Tehran
Province
Tehran
Postal code
1953643815
Phone
+98 21 2615 9477
Fax
Email
saharvaziri44@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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable