Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effect of probiotics with placebo on xerostomia in head and neck cancer patients undergoing radiation therapy

Protocol summary

Study aim

Comparison of unstimulated saliva flow in two probiotic and placebo groups Comparing the amount of stimulated saliva flow in two probiotic and placebo groups Comparison of dry mouth severity score (VAS) in two probiotic and placebo groups

Design

A controlled randomized trial, double blinded with a parallel group design of 82 patients (Phase 3). Randomization will be used by PASS program.

Settings and conduct

This study is conducted on patients with head and neck cancer who underwent radiotherapy in the last 1-3 months. After obtaining informed consent, these patients who referred to the Razi or Amiralmomenin Hospitals in Rasht will be enrolled. Patients are randomly assigned to one of the two intervention or control groups and receive the corresponding code inside the sealed envelope and receive the corresponding drug from the hospital pharmacist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All head and neck cancer patients who have had 1-3 months of radiotherapy; A functional level equal to or higher than 80 according to the Karnovsky criterion Non-entry criteria: Any other type of oral disease; Inability to understand the questionnaire; Parkinson; Sjogren; Diabetes; Acquired immunodeficiency syndrome; Use of drugs affecting saliva; Pregnancy; Taking antibiotics or probiotics in the last month

Intervention groups

The particpants of the intervention group receives a Lactogum troche before going to bed for 60 days. The mentioned drug is a product of Zist Takhmir company and contains the probiotic K12 and M18 strain of Streptococcus salivarius. The participants of the control group receives a placebo lozenge before going to bed for 60 days. The placebo is similar to Lactogum troche, but it does not contain probiotics.

Main outcome variables

volume of unstimulated saliva volume of stimulated saliva severity of xerostomia (Visual Analog Scale; VAS)

General information

Reason for update

In the initial version of the protocol, the sample size was estimated using G*Power based on an independent two-sample t-test, resulting in 64 participants per group. After a methodological revision and considering the correlated and serial structure of the continuous data, the statistical analysis was modified to a serial correlation model, which better aligns with the temporal nature of the data and the study objectives. Accordingly, the sample size was recalculated in G*Power and reduced to 41 participants per group (with 80% power and a 0.05 significance level). This change was made to improve statistical precision and ensure better alignment with the final analysis approach, without affecting the scientific validity of the study. It is also noted that this modification has been approved by the university’s research committee

Acronym

IRCT registration information

IRCT registration number: **IRCT20081202001483N5**
Registration date: **2022-08-03, 1401/05/12**
Registration timing: **prospective**

Last update: **2025-07-15, 1404/04/24**
Update count: **1**

Registration date

2022-08-03, 1401/05/12

Registrant information

Name

Mir Mohammad Jalali

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-01, 1401/06/10

Expected recruitment end date

2023-04-30, 1402/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of probiotics with placebo on xerostomia in head and neck cancer patients undergoing radiation therapy

Public title

Investigating the effect of probiotics on dry mouth after radiotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All head and neck cancer patients who had radiotherapy (after 1-3 months) Functional level equal to or higher than 80 according to the Karnofski criterion Absence of any other oral disease Inability to understand the questionnaire

Exclusion criteria:

Parkinson disease Sjögren's disease Taking drugs that affect the function of saliva Pregnancy Diabetes Acquired immune deficiency syndrome History of antibiotic use in the last 30 days Use of antifungal drugs or antiseptic mouthwashes

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

A statistician will generate independent allocation sequences and randomisation lists using the Power Analysis & Sample Size (PASS) software. Randomization will be performed in blocks of 4 (2 placebo and 2 probiotic) (21 blocks). To ensure allocation concealment, an independent person will oversee the packaging and labelling of trial treatments based on the randomisation schedule at otorhinolaryngology research center of Guilan University of Medical Sciences (GUMS). Zist Takhmir company (Tehran, Iran) provides the probiotic and placebo; the group assignment list will be withheld until the final evaluation of the study data. All investigators, participants, and outcome assessors will be blinded to the assigned treatment throughout the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Probiotics and placebo are prepared by Zyst Takhmir and are similar in terms of color, size and dimensions and packages. All the following drugs have a special code and are given to patients by the hospital pharmacist based on the assigned code in the randomization process. Patients and researchers and people who evaluate the results will not know about the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Amiralmomenin Hospital, 17 Sharivar street, Bank Melli Square

City

Rasht

Province

Guilan

Postal code

4139638459

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.GUMS.REC.1401.198

Health conditions studied

1

Description of health condition studied

Xerostomia

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion

Primary outcomes

1

Description

Volume of unstimulated saliva

Timepoint

At the beginning of the study (before the start of the intervention), at the end of 2 months and at the end of 3 months

Method of measurement

Measuring the amount of saliva for 5 minutes in unstimulated conditions

2

Description

Volume of stimulated saliva

Timepoint

At the beginning of the study (before the start of the intervention), at the end of 2 months and at the end of 3 months

Method of measurement

Measuring the amount of saliva for 5 minutes in stimulating conditions (using an applicator dipped in fresh lemon juice)

3

Description

Severity of xerostemia (Visual Analogue Scale; VAS)

Timepoint

At the beginning of the study (before the start of the intervention), at the end of 2 months and at the end of 3 months

Method of measurement

The patient chooses a score from 0 (absence of dry mouth) to 10 (worst degree of dry mouth) according to the severity of dry mouth.

Secondary outcomes

1

Description

Score of EORTC QLQ HN43

Timepoint

At the beginning of the study (before the start of the intervention), at the end of 2 months and at the end of 3 months

Method of measurement

using persian version of EORTC QLQ HN43 questionnaire

Intervention groups

1

Description

Intervention group: one probiotic lozenge (Lactogum) before going to bed for 60 days

Category

Treatment - Drugs

2

Description

Control group: one placebo lozenge before going to bed for 60 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr Hamid Saeidi Saedi

Street address

Razi square, Sardare Jangal Blvd

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4163934774

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2

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Maryam Akbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Dr Mohammadreza Naghipour

Street address
Deputy of Research and Technology of Guilan University of Medical Sciences- in front of 17 Shahrivar Hospital – Shahid Siadati Ave. – Namjoo St.

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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
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Dr Maryam Akbari

Position
Assisstant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In the case of individual patient data, all potential data will be shared after de-identifying individuals. The result of the clinical study will be published in the form of an article.

When the data will become available and for how long

The access period starts 6 months after publication of the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

For secondary data analysis and meta-analysis

From where data/document is obtainable

Dr Mir Mohammad Jalali Otorhinolaryngology research center, Amiralmomenin HospitalAmiralmomenin Hospital,17 sharivar street, Bank Mell square, Rasht , Iran. 4139638459 Tel: 0098 13 33238306 Mobile: 0098 9111318776 Email: mmjalali@gmail.com

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

After receiving the applicant's request and a brief statement of the protocol in which the mentioned information is used, a preliminary review will be done and the information will be sent to the researcher within 2 weeks.

Comments