Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of 1% pilocarpine mouthwash on salivation in patients undergoing head and neck radiotherapy: a double-blind randomized clinical trial

Protocol summary

Study aim

Due to its many side effects, pilocarpine tablets are not routinely prescribed in Iran for patients undergoing radiotherapy. The aim of this study was to evaluate the effect of pilocarpine as a mouthwash on patients undergoing radiotherapy.

Design

The clinical trial has a control group with randomized double-blind randomized parallel groups with phase 3 random allocation law on 62 patients.

Settings and conduct

It is a double-blind study that blindness will be performed for both therapists and treatable individuals. In this study, the target population will be all patients undergoing cervical radiotherapy referred to the radiotherapy ward of Shahid Madani Hospital in Tabriz.

Participants/Inclusion and exclusion criteria

In this double-blind randomized clinical trial, the study population included 62 patients with head and neck cancers (eg, locally advanced laryngeal cancer, locally advanced hypopharyngeal cancer, and oral and throat cancer). They will undergo radiotherapy in the radiotherapy center of Tabriz Civil Hospital.

Intervention groups

Both case and control groups will include 31 patients. The control group will be trained in salivary gland massage therapy and adequate hydration, and will be given a normal saline mouthwash, gargling thirty drops four times a day for 2 minutes. In the case group, in addition to the previously mentioned massage therapy training, pilocarpine hydrochloride mouthwash will be distributed, which will gargle 30 drops for 2 minutes four times a day. The intervention will continue for 2 weeks after radiotherapy.

Main outcome variables

Unstimulated salivary flow rate will be measured in four stages : two weeks before the first (basic) radiotherapy session, the first day of radiation therapy, and two and four weeks after radiation therapy.the amount of saliva (ml in 5 minutes) will be calculated and recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210830052335N1**
Registration date: **2021-09-09, 1400/06/18**
Registration timing: **prospective**

Last update: **2021-09-09, 1400/06/18**
Update count: **0**

Registration date

2021-09-09, 1400/06/18

Registrant information

Name

Paria Motahari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of 1% pilocarpine mouthwash on salivation in patients undergoing head and neck radiotherapy: a double-blind randomized clinical trial

Public title
The effect of 1% pilocarpine mouthwash on salivation in patients undergoing head and neck radiotherapy: a double-blind randomized clinical trial
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Head and neck cancers. Topical laryngeal cancer, hypopharyngeal cancer and nasopharyngeal cancer Under conventional radiation therapy with doses greater than 50 g Satisfaction to participate in the study
Exclusion criteria:
Changes in the patient's treatment protocol or process of receiving radiation therapy Lack of patient cooperation in the study process Taking any medication that reduces salivation, physical systemic diseases such as Sjogren's syndrome, diabetes, Behcet's disease, hypertension and hyperthyroidism
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be divided into case and control groups using a random allocation rule. In this way, 31 balls for the case group and 31 balls for the control group will be placed inside the lottery container and then the balls will be randomly recorded without being replaced from the container and the created sequence. To avoid selection bias, random assignment to Study groups will be hidden and this sequence will remain hidden until interventions are made.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is a double-blind randomized clinical trial in which blinding will be performed for both therapists and treatable individuals. After making the mouthwashes, they will be transferred and labeled in containers with the same shape and packaging, and only the number of mouthwashes and placebo will be recorded on the label (blinding of treatable people) and only one of the design colleagues who has the contents of the mouthwash Will know how to allocate patients in groups, will distribute mouthwashes among patients, and examination and collection of saliva samples will be performed by another project partner who does not know the type of patient group (blinding therapists).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tabriz University of Medical Sciences
Street address
Golgasht St. / Tabriz University of Medical Sciences, Central Building No. 2 / Third Floor, Vice Chancellor for Research and Technology
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-08-23, 1400/06/01
Ethics committee reference number
IR.TBZMED.REC.1400.499

Health conditions studied

1

Description of health condition studied
Xerostomia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Salivation rate
Timepoint
Two weeks before the first (basic) radiotherapy session, the first day of radiation therapy and two and four weeks after radiation therapy.

Method of measurement
For this purpose, the spitting method will be used in which patients refrain from drinking or eating anything for 90 minutes before sampling. Then, for 5 minutes, people will be asked to empty their saliva into a calibrated test tube once or twice a minute. The amount of saliva (ml in 5 minutes) will be calculated and recorded.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the case group, in addition to massage therapy training, pilocarpine hydrochloride mouthwash will be distributed, which will gargle 30 drops for 2 minutes four times a day. The intervention will continue for 2 weeks after radiotherapy.
Category
Prevention

2

Description
Control group: The control group will be trained in salivary gland massage therapy and adequate hydration, and they will be given a placebo mouthwash (normal saline), which will gargle 30 drops four times a day for 2 minutes each time. Which will be used for 2 weeks after starting radiotherapy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital, Tabriz
Full name of responsible person
Reza Eghdam Zamiri
Street address
Radiotherapy Department, Shahid Madani hospital, University Street, Tabriz
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5165655635
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+98 41 3334 7422
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reza_e_z@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mojgan kachoei
Street address
Department of Orthodontics, School of Dentistry , Tabriz University of Medical Sciences
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Phone
+98 41 3334 7422
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Dr.kachoei@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Paria Motahari
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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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
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
In this study, data on salivation in the two groups before and after the intervention will be published.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions Dentists

Under which criteria data/document could be used
If positive results are obtained, researchers can prepare this mouthwash according to the instructions and use it to prevent dry mouth in patients.

From where data/document is obtainable
Paria.motahari@yahoo.com 09144197584 Paria Motahari

What processes are involved for a request to access data/document
The applicant sends his request via email or phone number and information and data are sent to his email.

Comments