

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Investigating the role of injection of botulinum toxin in reserving the function of salivary gland in patients treated with neck radiotherapy

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Investigating the role of injection of Botulinum toxin in reserving the function of salivary gland in patients treated with neck radiotherapy

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Design

The role of botulinum toxin in prevention of xerostomia will be evaluated in this phase 2 clinical trial. Patients will enter in two groups including intervention (injecting toxin in submandibular gland before neck radiotherapy) and control (neck radiotherapy without further intervention). Xerostomia will be evaluated through scintigraphy before and after neck radiotherapy.

Registrant information

Name

Sepideh Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8879 6003

Email address

smansouri@ibcrc.ir

Settings and conduct

This study will be conducted in radiation-oncology ward of Imam Khomeini hospital. Patients who are referred for neck radiotherapy will be entered non randomized in intervention or control group.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age older than 18 years
Exclusion criteria: History of xerostomia
History of previous neck radiotherapy
History of collagen vascular disease

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2019-07-06, 1398/04/15

Intervention groups

Intervention group: patients should be injected by 50 units botulinum toxin (Ipsen) in submandibular salivary gland two weeks before radiotherapy. xerostomia should be evaluated through scintigraphy before and after radiotherapy. Control group: xerostomia should be evaluated through scintigraphy before and after radiotherapy.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Xerostomia

Trial completion date

empty

General information

Scientific title

Investigating the role of injection of botulinum toxin in reserving the function of salivary gland in patients treated with neck radiotherapy

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180225038862N1**

Registration date: **2019-03-09, 1397/12/18**

Public title

Administration of botulinum toxin in reserving the function of salivary gland in neck radiotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age older than 18 years

Exclusion criteria:

History of xerostomia History of previous neck radiotherapy History of collagen vascular disease

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

No 21, Dameshgh St. , Vali - e Asr Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1498789534589

Approval date

2018-05-23, 1397/03/02

Ethics committee reference number

IR.TUMS.VCR.REC.1397.043

Health conditions studied

1

Description of health condition studied

Malignant tumors of head and neck

ICD-10 code

C76.0

ICD-10 code description

Malignant neoplasm of head, face and neck

Primary outcomes

1

Description

Xerostomia

Timepoint

Xerostomia will be evaluated before starting radiotherapy and 6 months after finishing radiotherapy.

Method of measurement

Xerostomia will be evaluated through scintigraphy of sub-mandibular gland.

Secondary outcomes

1

Description

Constipation

Timepoint

Constipation will be evaluated before injection of toxin and 6 months after injection.

Method of measurement

Constipation will be evaluated through history.

Intervention groups

1

Description

Intervention group: patients will be injected by 50 units botulinum toxin in submandibular gland before neck radiotherapy.

Category

Treatment - Drugs

2

Description

Control group: patients will be irradiated without any intervention on the submandibular gland.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini cancer institute

Full name of responsible person

Dr Farshid Farhan

Street address

Imam Khomeini hospital, Bagherkhan ave., Tohid square

City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2536
Email
farhan@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-chancellor of research of Tehran university
Street address
Vice-chancellor of research of Tehran university,
Tehran university of medical sciences, Ghods street,
Keshavarz blvd.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 8163 3620
Email
research@ut.ac.ir
Web page address
<http://research.ut.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
Dr Farshid Farhan

Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Imam Khomeini hospital, Bagherkhan ave., Tohid square
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2536
Email
farhan@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Farshid Farhan
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Imam Khomeini hospital, Bagherkhan ave., Tohid square
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2536
Email
farhan@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Farshid Farhan
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address

Imam Khomeini hospital, Bagherkhan ave., Tohid square

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2536

Email

farhan@tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

Yes - There is 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

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

Design of the study and the study's report will be published in the article after finishing the study.

When the data will become available and for how long

The access will be 12 months after publication of the result.

To whom data/document is available

Data will be available for all.

Under which criteria data/document could be used

Data will be available if they will be referred to the article.

From where data/document is obtainable

Refer to the correspondent.

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

A request should be emailed to the correspondent.

Comments