

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of adjunctive effect grape seed extract(GSE) on oral mucositis in patients with a history of head and neck radiotherapy

Protocol summary

Study aim

Evaluation of grape seed extract on oral mucositis inpatients with head and neck radiotherapy history

Design

A randomized, double blinded, clinical trial with 50 patients in two group, 25 patients are intervention group and 25 patients are control group. Patients in the beginning day of radiotherapy received mouthwash with special code and followed for two weeks.

Settings and conduct

The patients in the Radiotherapy-Oncology Center of Shahid Madani hospital were recognized and in beginning of treatment they received a mouthwash with special code. Mouthwashes were two groups, one group is grape seed extract mouthwash and another group is placebo which were been coded by producer and patient and researcher didn't aware about the type of mouthwash. The patients were followed for two weeks and were examined in the first-5th-10th-14th days and the information was recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1-Complete consciousness 2-Ability of reading and writing 3-Oral mucus healthy 4-Total radiation more than 60 Gray in radiotherapy duration and 2 Gray radiation everyday Exclusion criteria 1-Respiratory system diseases and asthma 2-Diabetes 3-Autoimmune diseases 4-Fever and Neutropenia 5-Continuous usage of analgesics 6-Narcotic drug usage 7-Antibiotics usage 8-Using another mouthwash during investigation 9-Chemotherapy

Intervention groups

Patients receive 2% grape seed extract mouthwash in beginning day of radiotherapy to use for 2 weeks. Patients use mouthwash everyday 3 times and each time for 3 minutes. We examine the patients in first-5th-10th-14th days and record the observations. In control group we use placebo instead of mouthwash and patients use it for 2 weeks in the same way and we visit them and record the observations.

Main outcome variables

1-Mucositis intensity 2-Mucositis evaluation in first-5th-10th-14th days 3-Mucositis grading

General information

Reason for update

Acronym

G.S.E

IRCT registration information

IRCT registration number: **IRCT20181022041418N1**

Registration date: **2019-06-03, 1398/03/13**

Registration timing: **retrospective**

Last update: **2019-06-03, 1398/03/13**

Update count: **0**

Registration date

2019-06-03, 1398/03/13

Registrant information

Name

Javad Ahmadiadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3336 3311

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ahmadiadeh90@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-11, 1398/01/22

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of adjunctive effect grape seed extract(GSE) on oral mucositis in patients with a history of head and neck radiotherapy

Public title

Evaluation of grape seed extract effect on oral mucositis in patients with a history of head and neck radiotherapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete consciousness Ability of reading and writing
Oral mucus healthy Total radiation more than 60gray in radiotherapy duration and 2gray radiation everyday

Exclusion criteria:

Respiratory system diseases and asthma Diabetes
Autoimmune diseases Fever and Neutropenia Continuous usage of analgesics Narcotic drug usage Antibiotics usage Using another mouthwash during investigation Chemotherapy during investigation

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

At first 50 patients that have investigation standards are identified. Two types of mouthwash are prepared; type 1 is grape seed extract mouthwash(25 bottles) and type 2 is placebo(25 bottles). Both patient and researcher doesn't aware that use which type of mouthwash; only the producer of mouthwash can recognize the type of mouthwash with special codes. In the first day of radiotherapy each patient randomizely receive a bottle of mouthwash to use for two weeks. finally in the group study we have 50 patients that 25 of them have received grape seed extract mouth wash(intervention group) and 25 patients have received placebo(control group).

Blinding (investigator's opinion)

Double blinded

Blinding description

Two types of mouthwashes are being prepared; type 1 is grape seed extract mouthwash and type 2 is placebo. Both patient and researcher don't aware about the type of mouthwash; only the producer can recognize the type of mouthwash by special codes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz Univercity of Medical Sciences

Street address

Research-vice third floor, No 2 medical sciences Building Golgasht Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2018-09-22, 1397/06/31

Ethics committee reference number

IR.TBZMED.REC.1397.515

Health conditions studied**1****Description of health condition studied**

Post Radiation Mucositis

ICD-10 code

K12.33

ICD-10 code description

Oral mucositis (ulcerative) due to radiation

Primary outcomes**1****Description**

Mucositis intensity

Timepoint

First-5th-10th-14th days after mouthwash using

Method of measurement

Mucositis grading 0-4

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 25 patients whom will be treated under head and neck radiotherapy are being recognized and they receive 2% grape seed extract mouth wash which has been produced by Tabriz Drug Applied Center, patients use mouthwash everyday 3 times and each time for 3 minutes during 2 weeks. Patients are being examined in first-5th-10th-14th days and we record the observations.

Category

Treatment - Drugs

2

Description

Control group: 25 patients whom will be treated under head and neck radiotherapy are being recognized and they receive placebo which has been produced by Tabriz Drug Applied Center. Patients use placebo everyday during radiotherapy 3 times and each time for 3 minutes. Patients use placebo for 2 weeks and be examined in first-5th-10th-14th days and observations be recorded.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Shahid Madani radiation-oncology center

Full name of responsible person

Dr. Amir Ghasemi Jangjo

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hossein Babaei

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babaei42@yahoo.com

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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

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

Dr. Hossein Eslami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not 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

Yes - There is 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

Title and more details about the data/document

We share only the mucositis changes after using mouthwash.

When the data will become available and for how long

Data will be accessible one year after printing of the results.

To whom data/document is available

Both researchers and mouthwash producer companies can access the documents.

Under which criteria data/document could be used

In similar studies in patients with history of head and neck radiotherapy by changing the concentration of mouthwash and longer follow up it is possible. Also it is possible for evaluation the other effects of grape seed extract.

From where data/document is obtainable

1-Dr.Hosein Babaei Drug Applied Research Center
Golgasht Ave, Tabriz Tel:04133363311
Email:babaei42@yahoo.com 2-Dr.Javad Ahmadi Dentistry
faculty Golgasht Ave, Tabriz Tel:09144476091
Email:ahmadiadeh90@gmail.com

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

At first the applicant send her/his requisition to one of respondents and after surveying and confirmation of identity and ask about the intentions, the documents are available for him.

Comments