Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Radiotherapy and Oncology part, Shahid Madani Hospital Golgasht Ave

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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

Street address

Drug Applied Research Center, Golgasht Ave

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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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Person responsible for scientific inquiries

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