Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of miracle fruit effect on dysgeusia management in patients after chemotherapy

Protocol summary

Study aim
The aim of this study is to investigate the effect of miracle fruit on the improvement of taste disorder after chemotherapy.

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 135 patients. The rand function of Excel software was used for randomization.

Settings and conduct
135 patients referred to Deziani Hospital in Gorgan in 2023 will be included in the study in a simple randomized method regarding to the including criteria. Patients will be randomly divided into three groups of 45 people. The first group will receive a dose of 100 mg and the second group will receive a dose of 200 mg of miracle fruit capsules. The third group will be the control group that will receive a placebo. Patients take miracle fruit capsules 10 minutes before breakfast, lunch and dinner. After 14 days, the patients will answer the questions of the questionnaire and will be evaluated.

Participants/Inclusion and exclusion criteria
inclusion criteria: A cancer patient with the problem of taste disturbance after chemotherapy or radiotherapy treatment A patient with a probability of survival of more than six months Age above 18 years A patient with the ability to take oral medication Exclusion Criteria : Patients with taste disorder for any reason except chemotherapy and radiotherapy pregnant women History of allergy to berries A patient with oral cancer

Intervention groups
Patients will be divided into three groups of 45 people. The first group will receive a dose of 100 mg and the second group will receive a dose of 200 mg of miracle fruit capsules. The third group, the control group, will receive a placebo.

Main outcome variables
The primary outcome is the change in taste disorder; Secondary outcomes include the change of sour to sweet taste as well as the change in metallic taste sensation in patients' mouths

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230220057461N1**
Registration date: **2023-03-23, 1402/01/03**
Registration timing: **prospective**

Last update: **2023-03-23, 1402/01/03**
Update count: **0**

Registration date
2023-03-23, 1402/01/03

Registrant information

Name
Mahtab Golizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3255 1069

Email address
lona884@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of miracle fruit effect on dysgeusia management in patients after chemotherapy

Public title
miracle fruit effect on dysgeusia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A cancer patient with the problem of taste disturbance after chemotherapy or radiotherapy patient with survival rate more than 6 months patient over 18 years old A patient with the ability to take oral medication
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **135**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into three groups of 45 people, using a predetermined list, and each patient will be assigned a code. The first group will receive a dose of 100 mg and the second group will receive a dose of 200 mg of miracle fruit capsules. The third group, the control group, will receive a placebo. In the Excel software, we enter 45 items A, 45 items B and 45 items C in one column. In the opposite column, we generate random numbers using the rand() command and sort from small to large based on the values of the second column. One of the organizers of the project, who does not evaluate the results and knows that the letters A, B and C are related to medicine or placebo, sticks these letters on the bottles of medicine and placebo and based on the randomized list in Excel. It will be allocated to referring patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blind . The person evaluating the results of the study does not know which drug or placebo group the patient is placed in. The patient is also unaware that he is placed in the drug or placebo group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Gorgan University of Medical Sciences
Street address
Roya building , Mehrnegar 6 , Sayad 8 , Gorgan , Iran
City
Gorgan
Province
Golestan
Postal code
4917964404
Approval date
2023-01-08, 1401/10/18
Ethics committee reference number
IR.GOUMS.REC.1401.482

Health conditions studied

1

Description of health condition studied
parageusia
ICD-10 code
R43.2
ICD-10 code description
Parageusia

Primary outcomes

1

Description
Change in taste disorder
Timepoint
The beginning of the study and 14 days later
Method of measurement
questionnaire

Secondary outcomes

1

Description
Change of sour taste to sweet
Timepoint
The beginning of the study and 14 days later
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group1: The first intervention group consumes a dose of 100 mg of miracle fruit capsules after each meal.
Category
Rehabilitation

2

Description
Intervention group 2 : The second intervention group consumes a dose of 200 mg of miracle fruit capsules after each meal.
Category
Rehabilitation

3

Description
Control group: Control group patients will receive a placebo 10 minutes before breakfast, lunch, and dinner (3 times a day).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Deziani clinic , Gorgan
Full name of responsible person
Mahtab Golizadeh
Street address
Sayad 8 , Gorgan , Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Vice-Chancellor of Research and Technology (Dr Mirbehbahani)
Street address
Dental research Center, Gorgan Dental School, Shahriar 5, Shahriar town , Gorgan , Golestan province
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4913983635
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lona884@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Mahtab Golizadeh
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Mahtab Golizadeh

Position
Student

Latest degree
A Level or less

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Yes - There is 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
Potential data can be shared after de-identifying individuals

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

To whom data/document is available
Researchers working in academic and scientific institutions in the country can access the data of this study with a written request from the Research Center of Gorgan Dental School.

Under which criteria data/document could be used
The documents will be available to the applicants after obtaining the permission from the project managers and the research director of the Golestan Faculty of Medical Sciences and with a written request from the research center of the Gorgan Dental Faculty. It is obvious that administrative procedures take time and we try to do it within 1 month from the date of the request.

From where data/document is obtainable
Gorgan, Shahrek Shahryar, Shahryar 5, Gorgan Faculty of Dentistry, Dental Research Center, Mrs. Shabani, Research Center Expert, Postal Code 4913983635, Phone Number: 01728853262, Email: s.shabani8791@gmail.com

What processes are involved for a request to access data/document
Researchers working in academic and scientific institutions in the country can access the data of this study with a written request from the research center of the Gorgan Faculty of Dentistry. The research of Gorgan Dental School will be available to the applicants. It is obvious that administrative procedures take time and we try to do it within 1 month from the date of the request.

Comments