

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Sayad 8 , Gorgan , Iran

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Email

lona884@yahoo.com

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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Gorgan

Province

Golestan

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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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Full name of responsible person

Mahtab Golizadeh

Position

Student

Latest degree

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Person responsible for updating data

Contact

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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