Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of syrup of Debs (Grape product) on breast cancer-related fatigue in breast cancer patients: A randomised control trial

Protocol summary

Study aim
Effects of syrup of Debs (Grape product) on cancer-related fatigue in breast cancer patients: A randomised control trial

Design
Two arm parallel group randomized clinical trial, Double-blinded

Settings and conduct
60 breast cancer patients 18 to 70-year-old that are undergoing chemotherapy will enter the study. Based on entry criteria, they will be entered in the study. Patients will be divided into two groups by simple random method. Group (A) will receive drug (Debs Syrup), Group (B) will receive placebo (placebo Syrup). The dose of the drug will be given 3 cc three times a day and follow-up at weeks 0 and 4 and second week we will have telephones follow up

Participants/Inclusion and exclusion criteria
Patients women with cancer Having at least 18 years and maximum 80 years Having symptoms of fatigue Having at least 8 g/dl Hemoglobin Having at least 30% Hematocrit Having at least 2mg/dl Billy Rubin Having at least 2mg/dl Creatinine Having normal TSH

Intervention groups
There are two intervention groups in this study, one group gets a Debs Syrup, and the other group receives the placebo Syrup.

Main outcome variables
Chemotherapy Induced Fatigue score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190708044149N1**
Registration date: **2020-01-28, 1398/11/08**
Registration timing: **registered_while_recruiting**
Last update: **2020-01-28, 1398/11/08**
Update count: **0**

Registration date
2020-01-28, 1398/11/08

Registrant information

Name
Reyhaneh Gharehgozlou

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8877 3521

Email address
reyhangh792@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-30, 1398/04/09

Expected recruitment end date
2020-02-28, 1398/12/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of syrup of Debs (Grape product) on breast cancer-related fatigue in breast cancer patients: A randomised control trial

Public title
Effects of syrup of Debs on fatigue in breast cancer patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients women with Breast cancer Having at least 18 years and maximum 80 years Having symptoms of fatigue Having at least 8 g/dl Hemoglobin Having at least 30% Hematocrit Having at least 2mg/dl Billy Rubin Having at least 2mg/dl Creatinine Having normal TSH
Exclusion criteria:
Severe Hb drop during study Severe Platelets and white blood cell loss during the study change of treatment

Age
From **18 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization: The numbers from 1 to 60 is written on 60 papers and placed inside a bag. Each time a patient enters the study according to entry criteria, a paper is removed from the bag and the number that is written on the paper will be the number of intervention medication.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drug and placebo are coded, patient and researcher are blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee on Biomedical Research of Shahid Beheshti University of Medical sciences

Street address
Shahid Beheshti University of Medical sciences, Daneshju Blv.

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2019-06-29, 1398/04/08

Ethics committee reference number
IR.SBMU.CRC.REC.1398.002

Health conditions studied

1

Description of health condition studied
Fatigue related breast cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fatigue severity score based on fatigue eye scale criterion

Timepoint
Zero and 4 weeks after treatment

Method of measurement
Fatigue Eye Scale Criterion Questionnaire

2

Description
Fatigue severity score

Timepoint
Zero and 4 weeks after treatment

Method of measurement
Fatigue severity scale questionnaire

3

Description
Cancer Fatigue Scale Score

Timepoint
Zero and 4 weeks after treatment

Method of measurement
Cancer Fatigue Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Fatigue patients with breast cancer receiving 10 cc syrup three times daily for four weeks

Category
Treatment - Drugs

2

Description

Control group: Fatigue patients with breast cancer receiving 10 cc placebo three times daily for four weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Dr. Ghazaleh Heydarirad

Street address

Shahrdari st, Tehran

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1989934148

Phone

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Pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Somayeh Esmaeili

Street address

Shams Alley, Vali-e-Asr Street, Shahid Beheshti University of Medical Sciences

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Grant name

Research Assistant of Shahid Beheshti University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ghazaleh Heydarirad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic data and the result of the clinical trial

When the data will become available and for how long
6 month later

To whom data/document is available
Researchers

Under which criteria data/document could be used
After publication of the extracted article of the clinical trial

From where data/document is obtainable
Sending Email to the researchers

What processes are involved for a request to access data/document
Sending the request via the email

Comments