

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect Of Consumption Of grape syrup,saffron and omani lemon(debs) on postpartum fatigue in hospitals of Shiraz University of Medical Sciences in 2022.

Protocol summary

Study aim

Assessing the effect of consumption Of grape syrup,saffron and omani lemon(debs) on postpartum fatigue

Design

Clinical trials with control group and with parallel groups, triple blind randomized, phase 2-3 on 100 people will be done using excel software for randomization

Settings and conduct

Sampling will be done in hospitals of Shiraz University of Medical Sciences.The study is triple blind.

Participants/Inclusion and exclusion criteria

1-Mothers aged 18-40 who are capable of participating in the study with their own satisfaction. 2- Mother and infant have no underlying diseases. 3- Mother should be primigravida and have basic literacy. 4-The infant should be full-term and singleton. 5- Infant should be between 2500-4000 gr. 6- Mother should not have abnormal bleeding after labor. 7- Mother should pass a low-risk pregnancy. 8- Mother's BMI should be ≤ 30 (not be obese). 9- Delivery should not be difficult using vacuum or forceps. ; Exclusion criteria: 1- Mother's severe postpartum bleeding.2-Possible sensitivity to syrup.3-not willing participants to continue the study.

Intervention groups

Intervention group: Active drug (grape, saffron, and Omani lemon syrup), control group: Placebo

Main outcome variables

postpartum fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200815048407N2**
Registration date: **2022-02-07, 1400/11/18**

Registration timing: **prospective**

Last update: **2022-02-07, 1400/11/18**

Update count: **0**

Registration date

2022-02-07, 1400/11/18

Registrant information

Name

Mahboobe Mojtahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4223 6150

Email address

mojtahedi.mahboobe@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Consumption Of grape syrup,saffron and omani lemon(debs) on postpartum fatigue in hospitals of Shiraz University of Medical Sciences in 2022.

Public title

The Effect Of Consumption Of grape syrup,saffron and

omani lemon(debs) on postpartum fatigue

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Mothers are between 18-40 years old. Mother and infant have no underlying diseases. The infant should be full-term and singleton. Infant should be between 2500-4000 gr. Mother should not have abnormal bleeding after labor. Mother's BMI should be ≤ 30 (not be obese). Mother should pass a low-risk pregnancy. Delivery should not be difficult using vacuum or forceps. Mother should be primigravida and have basic literacy.
Exclusion criteria:
 Women with heavy postpartum bleeding. Possible sensitivity to syrup

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
 In order to randomize and allocate individuals to groups, random number function will be used. Randomization is as follow using excel software: first, groups will be entered in one column as A,B together; as the number of samples in each group has been defined as 50 (including sample drop), thus, B, A, should be entered in order and beneath. In the other column , using the command RAND , the random numbers are generated . In the next step, using the command sort, the generated random numbers will be organized ranging from lowest numbers to highest ones or vice versa, this will result a change in groups order as A, B. using the new order, individuals will be allocated to different groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
 The study is triple blind. This means that the researcher, participants, and statistic consultant will have no information about the drugs used by each group or each A or B syrup filled with which type of drugs.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of assistance of research and technology of Shahid Beheshti University of Medical S

Street address

Niyayesh Intersection, Valiasre Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-09-11, 1400/06/20

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.496

Health conditions studied

1

Description of health condition studied

postpartum fatigue

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

postpartum fatigue

Timepoint

1,3,10,30,42 days after deliver

Method of measurement

Multidimensional Fatigue Assessment Questionnaire and Krap et al.'s Fatigue Intensity Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: syrup contains grape juice,saffron and dried lime / each12 hours 10cc for 6 weeks / the syrups will be provided at School of Traditional Iranian Medicine of Shahid Beheshti University of Medical Sciences

Category

Treatment - Drugs

2

Description

Control group: placebo syrup /each 12 hours 10cc for 6 weeks/ the syrups will be provided at School of Traditional Iranian Medicine of Shahid Beheshti University of Medical Sciences

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospita

Full name of responsible person

Babak Hoseini

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2

Recruitment center

Name of recruitment center

Shoushtari hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Homa Hajimahdipoor

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.

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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

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

Mahboobe Mojtahedi

Position

MSc student

Latest degree

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Person responsible for scientific inquiries

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Mojgan Tansaz

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Person responsible for updating data

Contact

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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

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When the data will become available and for how long

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To whom data/document is available

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Under which criteria data/document could be used

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From where data/document is obtainable

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

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Comments