

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the incidence of postpartum depression in "primiparous women receiving grape juice" and the control group

Protocol summary

Study aim

prevention of postpartum depressive

Design

A clinical trial with a control group, randomized with a random number table, on 68 primiparous women.

Settings and conduct

This clinical trial will be performed on 68 eligible women referred to Shahid Sadoughi Hospital in Yazd, who were in the first day after delivery, and after completing the single consent form, they will be randomly placed in the intervention or control group using a random number table. Grape juice is obtained from the Khorramasia Rahavaran factory, which produces grape molasses industrially and is licensed by the Ministry of Health. The intervention group will be prescribed 15 grams of oral grape molasses twice a day, from the first day after delivery to 30 days after delivery, but the control group will not be prescribed grape molasses. 1 and 3 months after delivery, people in both groups will be contacted to fill out the Edinburgh Questionnaire by telephone. Both groups will be assessed for their average Edinburgh score and the incidence of depression.

Participants/Inclusion and exclusion criteria

Entry conditions: First pregnancy experience
Exclusion criterion: Allergy to grape molasses
Taking antidepressants, anti-anxiety and anti-stress drugs
Having gestational diabetes or other diabetes
Having a contraindication to carbohydrates

Intervention groups

This clinical trial will be performed on primiparous women. The intervention group will receive 15 grams of grape molasses twice a day from the first day after delivery until 30 days later. But the control group will not receive grape molasses.

Main outcome variables

The Postpartum Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140817018828N8**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

Alimohammad Ranjbar

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3419

Email address

amranjbar@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-17, 1400/01/28

Expected recruitment end date

2021-10-20, 1400/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the incidence of postpartum depression in "primiparous women receiving grape juice" and the control group

Public title

Evaluation of grape- molasses on prevention of postpartum depressive in primiparous women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

First pregnancy experience Having Iranian nationality Score less than 13 on the Edinburgh Questionnaire women between the age of 20 – 35 years

Exclusion criteria:

Allergy to grape molasses unwanted pregnancy Taking antidepressants, anti-anxiety and anti-stress drugs Having gestational diabetes or other diabetes Having preeclampsia during pregnancy Alcohol or drug use by the mother Having medical disorders such as severe vomiting and nausea Having a known systemic and chronic disease History of infertility Having drug allergies Having a contraindication to carbohydrates

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

random number table: Each person is assigned a 2-digit code from 01 to 68, respectively. Using a random table of numbers, "34 two-digit numbers less than 69" are selected, and each person whose code is between these 34 numbers is given grape molasses.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of

Medical Sciences

Street address

Boulevard of Shohadaye gomnam

City

YAZD

Province

Yazd

Postal code

00

Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.292

Health conditions studied

1

Description of health condition studied

Postpartum Depression

ICD-10 code

F-53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

Postpartum Depression Score in the Edinburgh Questionnaire

Timepoint

The first day, 1 and 3 months after delivery

Method of measurement

Edinburgh Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to receiving routine postpartum care, this group eats 15 grams of grape molasses by 15 cc modules twice daily (morning and evening) from the first day after delivery to 30 days after delivery (for 30 days). grape molasses is prepared from Khorramsahia factory, which is produced industrially.

Category

Prevention

2

Description

Control group: This group will receive only routine postpartum care and will not receive grape molasses from the first day after delivery until 30 days later.

Category
Prevention

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital of Yazd
Full name of responsible person
Sedigheh Kardan
Street address
Ibn Sina Street
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Postal code
8916886938
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kardan.sedigheh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Hooshang Mehrparvar
Street address
Bahonar Square, Yazd, Iran
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8917693571
Phone
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Email
ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Alimohammad Ranjbar Jamalabadi
Position
associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Sedigheh Kardan

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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