Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Saffron versus placebo on prevention of postpartum blues in primiparous women referring: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of saffron versus placebo on prevention of postpartum blues in primiparous women referring

Design
This is a double-blind randomized clinical trial, phase II, in which 100 eligible primiparous women will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible primiparous women referring to the Comprehensive Health Centers in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age:18 to 35 years old; primiparous; singleton; term pregnancy; wanted pregnancy; the first marriage; normal delivery. Exclusion criteria: mental disease; chronic diseases such as diabetes, hypertension, cardiovascular disease; history of infertility; hospitalization of the newborn in the intensive care unit.

Intervention groups
Intervention group: routine postpartum care plus saffron capsule (manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) daily for 14 days. Control group: routine postpartum care plus placebo capsule (manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) daily for 14 days.

Main outcome variables
Mean score of postpartum blues

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N336**
Registration date: **2020-01-27, 1398/11/07**
Registration timing: **prospective**

Last update: **2020-01-27, 1398/11/07**
Update count: **0**

Registration date
2020-01-27, 1398/11/07

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-20, 1398/12/01

Expected recruitment end date
2020-06-19, 1399/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Saffron versus placebo on prevention of

postpartum blues in primiparous women referring: a double-blind randomized clinical trial

Public title
Effect of Saffron versus placebo on prevention of postpartum blues in primiparous women referring
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 35 years Primiparous Singleton Term pregnancy Wanted pregnancy The first marriage Normal delivery
Exclusion criteria:
Mental disease Chronic diseases such as diabetes, hypertension, cardiovascular disease, History of infertility Hospitalization of the newborn in the intensive care unit
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs will be given in coded envelops. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2020-01-11, 1398/10/21
Ethics committee reference number
IR.UMSHA.REC.1398.863

Health conditions studied

1

Description of health condition studied
Postpartum blues
ICD-10 code
O90.6
ICD-10 code description
Postpartum mood disturbance

Primary outcomes

1

Description
Mean score of postpartum blues
Timepoint
Before the intervention and on 1, 5, 10 and 14 days after the intervention
Method of measurement
Using General Health Questionnaire (GHQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine postpartum care plus saffron capsule (manufactured by laboratory of School of Pharmacy, Hamadan University of Medical Sciences) daily for 14 days
Category
Treatment - Drugs

2

Description
Control group: Routine postpartum care plus placebo capsule (manufactured by laboratory of School of Pharmacy, Hamadan University of Medical Sciences) daily for 14 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Centers in Hamadan city
Full name of responsible person
Mahtab Satari
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Hamedan 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
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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
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