

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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 envelopes. 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

##### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0572

##### Email

mahtabsattari212@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0717

##### Email

info.research@umsha.ac.ir

##### 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Mahtab Satari

##### Position

Midwifery Student

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0572

##### Email

mahtabsattari212@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Arezoo Shayan

##### Position

Master of Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

**Phone**

+98 81 3838 0572

**Email**

arezoo.shayan2012@yahoo.com

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone****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