Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Investigation into the effectiveness of Crocus savitus and its active ingredient Crocin as a complementary approach in the treatment of patients with major postpartum depression receiving treatment, using triple blind random clinical trial controlled with placebo, plus assessment of the change in patients' Beck II score.

Protocol summary

Study aim
Investigation of the therapeutical effects of Saffron and Crocin in treatment of post partum depression as an alternative approach
Design
Three arm parallel group design of 45 patients, randomized trial with control
Settings and conduct
The research will be carried out as triple blind, researcher, physician and patients will be unaware, at Mashhad's Ibn Sina hospital
Participants/Inclusion and exclusion criteria
Inclusion criteria; nursing mothers with post partum depression. Exclusion criteria; hepatic and renal disorder, history of being allergic to saffron, alcohol consumption and drug use
Intervention groups
First intervention group: Take tablets containing 15mg Saffron BID besides main medication for 3 months Second intervention group: Take tablets containing 5 mg Crocin BID besides main medication for 3 months Third intervention group: Control group with pelacbo's besides main medication for 3 months
Main outcome variables
Assessment of the treatment according to changes in Beck2's score average

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130826014477N5**
Registration date: **2018-08-01, 1397/05/10**
Registration timing: **prospective**

Last update: **2018-08-01, 1397/05/10**
Update count: **0**
Registration date
2018-08-01, 1397/05/10

Registrant information
Name
Zhila Taherzadeh
Name of organization / entity
Mashhad 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
2018-08-06, 1397/05/15
Expected recruitment end date
2019-06-05, 1398/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation into the effectiveness of Crocus savitus and

its active ingredient Crocin as a complementary approach in the treatment of patients with major postpartum depression receiving treatment, using triple blind random clinical trial controlled with placebo, plus assessment of the change in patients' Beck II score.

Public title
Comparison between the effectiveness of Crocus sativus and Crocin in the treatment of patients with major postpartum depression under common medical care.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Nursing mothers after their delivery up to the passage of six months Nursing mothers in the 18-50 age range Delivery of full-term, healthy, singleton baby Acceptance of completion of the informed consent form after providing the necessary information on the investigation Obtaining of an exact diagnosis of the major depressive disorder using Edinburgh questionnaire by a psychiatrist during a clinical examination
Exclusion criteria:
Patients with a history of chronic, systemic diseases Patients with a history of medical disorders such as preeclampsia and diabetes Patients allergic to saffron Smoking cigarettes, drinking alcohol and taking drugs Patients with a history hepatic and renal disorders
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple, individual, unstratified randomization using randomization website's random number list and sealed envelope
Blinding (investigator's opinion)
Triple blinded
Blinding description
After all the patients are diagnosed as suffering from postpartum depression by a psychiatrist, they are divided randomly into three groups by an academic individual with knowledge of scientific methods not taking part in the investigation, and their sealed envelope of medications for a period of two weeks and Beck II questionnaire are distributed among the patients by another individual other than the investigator, clinical health care provider and outcome analyst, then the collected data is handed to the investigator.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
School of pharmacy, Pardis university campus, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
917751365
Approval date
2018-05-12, 1397/02/22
Ethics committee reference number
IR.MUMS.REC.1397.043

Health conditions studied

1

Description of health condition studied
major postpartum depression
ICD-10 code
F53.1
ICD-10 code description
Severe mental and behavioural disorders associated with the puerperium, not elsewhere classified Puerperal psychosis NO

Primary outcomes

1

Description
Change in mean score of BDI-II
Timepoint
Every two weeks for12 weeks
Method of measurement
BDI_II Questionnaire

Secondary outcomes

1

Description

Investigation on alternative medicine on females' sexual function

Timepoint

Beginning of intervention and end of every months

Method of measurement

FSFI Questionnaire

2

Description

Monitor of, investigation into and finding evidence for completing probable adverse effects of using Corcus Sativus and Crocin in nursing mothers to add to drug's information in herbal pharmacopeia

Timepoint

Beginning of intervention and end of every months during patient's visit for a period of twelve weeks

Method of measurement

Observation and clinical examination of the patient

3

Description

Examining patients' response to the alternative medicine

Timepoint

At the end of intervention

Method of measurement

Assessment of patients' number with fifty percent decrease in average score Beck II questionnaire in comparison with the base line

4

Description

Examining patient's remission under treatment

Timepoint

The end of intervention

Method of measurement

Assessment of patients' number with seventy percent decrease in average score Beck II questionnaire in comparison with the base line

5

Description

Assessment of the effects of such interfering factors as age, treatment protocol, type of delivery and etc.

Timepoint

The end of intervention

Method of measurement

Statistical analysis of collected data with SPSS software

Intervention groups

1

Description

Control group: Using placebo alongside the patient's main drug regimen

Category

Placebo

2

Description

Second intervention group: Tablets containing five mg Crocin (prepared in the Pharmacy faculty of Mashhad Medical University) taken orally twice a day for three months

Category

Treatment - Drugs

3

Description

First intervention group: Tablets containing fifteen mg saffron (prepared in the Pharmacy faculty of Mashhad Medical University using Mashhad Saharkhiz company's saffron) taken orally twice a day for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina psychiatry training hospital

Full name of responsible person

Fatemeh Behdani

Street address

Ibn Sina hospital, Hor Ameli Street, Adjacent to Astan Qods' transport

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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
Mashhad University of Medical Sciences

Proportion provided by this source
90

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
Mashhad University of Medical Sciences

Full name of responsible person
Zhila Taherzadeh

Position
Assisstant professor

Latest degree
Ph.D.

Other areas of specialty/work
Clinical pharmacology

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Pharmacy student

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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
Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

After the participants' identities are obscured, all the data are publitionable.

When the data will become available and for how long

The finalized data begin to be available for access after the research is finished.

To whom data/document is available

All the data are available to be sent to the applicants if their request is confirmed.

Under which criteria data/document could be used

Universities' and researchers permission

From where data/document is obtainable

To the faculty member who is the trials' operator taherzadehzh@mums.ac.ir 09158867923

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

Sending of the written request Attainment of approval from the university and the involved faculty member

Comments