

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 placebo'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

Country

Iran (Islamic Republic of)

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+98 51 1882 3255

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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

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Mashhad

Province

Razavi Khorasan

Postal code

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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 for 12 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

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Clinical pharmacology

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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 publicationable.

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