Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Investigating the effect of Citrus Aurantium blossom on anxiety in the last month of pregnancy and reducing postpartum depression

Protocol summary

Study aim
Determining the effect of Citrus aurantium capsule on anxiety in the last month of pregnancy and childbirth

Design
Randomized parallel-group trial with a control group, double-blind with blinding of all participants, investigators, and staff, phase 3 on 100 patients.

Settings and conduct
100 pregnant women at Hajar hospital eligible for including the study who are willing to participate will be recruited. Next, the goals of the study, instructions on how to fill the questionnaire, and the measures that would be taken to ensure patient's privacy will be explained to them and the checklist will be filled. Then they will be visited by a psychiatrist and after confirming anxiety, they will enter the study and be allocated to intervention or control group randomly. The Beck anxiety inventory will be filled by the participants two more times; after childbirth and 2 weeks postpartum. Envelopes containing Citrus aurantium capsules and placebo will be prepared by an independent individual and will look completely identical. So participants and investigators are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18 to 35 years old, informed consent, literate, no history of allergy to herbal medicine, a low-risk pregnancy. Exclusion criteria: chronic diseases; addiction or substance abusers.

Intervention groups
Intervention group: Citrus aurantium 500mg BID taken orally beginning at 36th pregnancy week and continue to two weeks postpartum. Control group: placebo (starch capsules) taken orally BID.

Main outcome variables
Beck anxiety inventory score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210926052594N1**
Registration date: **2021-10-09, 1400/07/17**
Registration timing: **prospective**

Last update: **2021-10-09, 1400/07/17**
Update count: **0**

Registration date
2021-10-09, 1400/07/17

Registrant information

Name
Fateme Ahmadinia

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 4262 0710

Email address
fateme.ahmadiniaa@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-12, 1400/07/20

Expected recruitment end date
2021-11-11, 1400/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Citrus Aurantium blossom on anxiety in the last month of pregnancy and reducing postpartum depression

Public title
Citrus Aurantium and anxiety in the last month of pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent Being literate Being over 36 weeks pregnant Low-risk pregnancy
Exclusion criteria:
History of allergy to herbal medicines History of chronic disease Addiction or drug abuse
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the “generate numbers” section of the randomizer.org website, 100 numbers will be generated from 1000 to 100000 for the participants’ list, and even and odd numbers will be assigned to either the intervention or control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants will be kept blinded to which treatment they are receiving. Investigators and staff will be kept blind to participant assignment. Procedures will be implemented to maintain separation between staff members that take outcome measurements and staff to deliver the intervention. Staff who obtain outcome measurement will not be informed of the group assignment. Investigation staff who will deliver the intervention will not take outcome measurements.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Sciences, Rahmatie, Shahrekord
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Approval date
2021-04-06, 1400/01/17
Ethics committee reference number
IR.SKUMS.REC.1400.006

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Beck anxiety score
Timepoint
Baseline, immediately after delivery, 2 weeks postpartum
Method of measurement
Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 500mg Citrus aurantium capsules taken orally BID for 6 weeks (from the 36th week of pregnancy to 2 weeks postpartum)
Category
Treatment - Drugs

2

Description
Control group: placebo capsules (starch) taken orally BID for 6 weeks (from the 36th week of pregnancy to 2 weeks postpartum)
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar hospital
Full name of responsible person
Fateme Ahmadinia
Street address
Hajar hospital, Parastar st., Shahrekord
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8716754633
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ramila.nour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghi
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Shahrekord University of Medical Sciences, Rahmatie, Shahrekord.
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Moavenattahghigh@skums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Fateme Ahmadinia
Position
Resident
Latest degree
Medical doctor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected deidentified IPD will be shared.
When the data will become available and for how long
Data files will be available starting 6 months after publishing the results.
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
No specific criteria
From where data/document is obtainable
Requests will be received at ramila.nour@gmail.com
What processes are involved for a request to access data/document
Requests will be reviewed by our correspondent and the requesters will be notified shortly.
Comments