

# 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 Ahmadiania

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 4262 0710

##### Email address

fateme.ahmadianiaa@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 Ahmadiania

**Street address**

Hajar hospital, Parastar st., Shahrekord

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8716754633

**Phone**

+98 38 3224 3715

**Email**

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

**Street address**

Shahrekord University of Medical Sciences, Rahmatie,  
Shahrekord.

**City**

Shahrekord

**Province**

Isfahan

**Postal code**

8815713471

**Phone**

+98 38 3334 2414

**Email**

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 Ahmadiania

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No. 38, Danesh St., Najafabad

**City**

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**Province**

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**Postal code**

8513743973

**Phone**

+98 938 793 2492

**Email**

Fateme.ahmadianiaa@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

Resident

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

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Shahre-kord University of Medical Sciences

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**Email**

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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**