

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effectiveness of Citrus Aurantium distillate on anxiety and sleep disorders in mothers with infants

Protocol summary

Study aim

The Effect of Citrus Aurantium distillate on Anxiety and Sleep Disorder in mothers with neonate admitted to neonatal intensive care unit

Design

The clinical trial will have a control group and an intervention group, a randomized controlled trial, a method of randomization of permutation blocks and a sample size of 60 people.

Settings and conduct

This study is a two-group clinical trial performed on mothers with infants admitted to the NICU ward at home. In this study, all mothers of newborns who are hospitalized in Amirkola and Ayatollah Rouhani Babol pediatric hospitals in NICU during 2021, are considered as the study population and enter the study if satisfied.

Participants/Inclusion and exclusion criteria

Inclusion criteria: be literate; no history of mental illness in the mother; 7 days have passed since the baby was admitted; score of 43 or higher on the General Sleep Disorder Scale; lack of sensitivity to medicinal plants and food; no pregnancy complications such as diabetes and eclampsia and heart problems; no previous history of premature infants or hospitalized infants Exclusion criteria: infant hospitalization less than 14 days in the neonatal intensive care unit; the mother's unwillingness to continue participating in the study; occurrence of unpleasant events for the mother; maternal sensitivity to orange spring sweat.

Intervention groups

Intervention group A will consume Citrus Aurantium distillate syrup and group B will be the control group who will be given syrup prepared from water and sugar.

Main outcome variables

Mothers' anxiety; maternal sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201209049666N1**
Registration date: **2021-04-15, 1400/01/26**
Registration timing: **prospective**

Last update: **2021-04-15, 1400/01/26**

Update count: **0**

Registration date

2021-04-15, 1400/01/26

Registrant information

Name

Zahra Dehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3272 6106

Email address

zahra.dehghan@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-03, 1400/02/13

Expected recruitment end date

2022-01-03, 1400/10/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Citrus Aurantium distillate on anxiety and sleep disorders in mothers with infants

Public title

The Effect of Citrus Aurantium distillate on Anxiety and Sleep Disorder in mothers with neonate admitted to neonatal intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having literacy No history of disease 7 days have passed since the baby was admitted Score 43 or higher General Sleep Disorder Lack of sensitivity to plants No history of premature infants Not having various problems in pregnancy such as heart disease and ...

Exclusion criteria:

Infant hospitalization less than 14 days in the neonatal intensive care unit The mother's unwillingness to continue participating in the study Occurrence of unpleasant events for the mother Maternal sensitivity to orange spring sweat

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Mothers were divided into two equal and identical groups using the method of randomization of permutation blocks. First, blocks of size 4 consisting of two A and two B are created. In each block, the order of receiving A and B will be random. In a table of 60 cells, all four permutations of the two interventions will be randomized. A three-digit code is assigned to each house to hide the allocation process using a random number table.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganj Afrooz St.

City

Babol

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Mazandaran

Postal code

4717647745

Approval date

2020-11-20, 1399/08/30

Ethics committee reference number

IR.MUBABOL.REC.1399.393

Health conditions studied**1****Description of health condition studied**

Sleep Disorders

ICD-10 code

G47.8

ICD-10 code description

Other sleep disorders

2**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**

The effect of Citrus Aurantium Sweat on anxiety in mothers with infants

Timepoint

Before the intervention and after the last day of the intervention

Method of measurement

The State-Trait Anxiet Inventory

2**Description**

The effect of orange spring sweat on the rate of sleep disorders in mothers with infants

Timepoint

Before the intervention and after the last day of the intervention

Method of measurement

General Sleep Disturbance Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Citrus Aurantium distillate 500 mg, twice daily + Fluoxetine 20 mg daily for 7 days

Category

Treatment - Other

2

Description

Control group: Fluoxetine 20 mg daily plus placebo (Water + sugar)for 7 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola Hospital, Babol

Full name of responsible person

Zahra Dehghan

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Amirkola Children's Hospital, Darolshafa St., Imam Khomeini St.

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research, Babol 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

Babol University of Medical Sciences

Full name of responsible person

zahra Dehghan

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

No - There is not 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

No - There is not 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

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

One year after printing

To whom data/document is available

All researchers

Under which criteria data/document could be used

Students only to advance their dissertation work

From where data/document is obtainable

zahra dehghan shdehghan29@gmail.com

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

Have a valid scientific degree

Comments