Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

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+98 11 3272 6106

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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
Province
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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Recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
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Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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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