Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Investigation and Comparing the effects of foot reflexology and sucrose 24% with pacifier on severity of neonatal Abstinence syndrome, Hearth rate and Respiratory rate among the neonates with addicted mother

Protocol summary

Study aim
Determining and comparing the effect of reflexology and sucrose with pacifier on severity of substance withdrawal syndrome symptoms in addicted infants

Design
Double-blind clinical trial, block randomization in terms of substance consumption, Fingan score and type of food, with control group, on 90 addicted infants, two intervention groups and one control group in parallel

Settings and conduct
This study will be performed in Pasteur Hospital of Bam city and includes two intervention groups and a control group. Participants are blind (blindness is based on the fact that they are infants) and will be intervened in a separate room. It will also be blind .Reflexology intervention will be performed for minutes. The basis of finger work is walking. In the sucrose group with the pacifier, pour 2 cc of sucrose solution on the front of the baby's tongue, followed by placing the pacifier in the baby's mouth for 15 minutes. The control group will have only the presence of the intervener. Interventions will be performed twice a day for 12 hours. Heart rate, respiration rate and deprivation syndrome score are measured before the intervention and then 15 minutes and 2 hours after the intervention.

Participants/Inclusion and exclusion criteria
Term addicted babies Get a score of 8 or higher on the Finigan checklist hospitalized Lack of congenital problems and problems affecting the symptoms of deprivation Parental consent

Intervention groups
Reflexology : Babies will receive a foot massage for 15 minutes Sucrose : Pour 2 cc of sucrose solution on the baby's tongue with a sterile syringe, followed by placing the pacifier in the baby's mouth for 15 minutes. Control : will have only the presence of the interferer

Main outcome variables
neonatal Abstinence syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131228015965N20**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

Registration date
2020-09-01, 1399/06/11

Registrant information

Name
Majid Kazemi

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-22, 1398/07/30

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and Comparing the effects of foot reflexology and sucrose 24% with pacifier on severity of neonatal Abstinence syndrome, Hearth rate and Respiratory rate among the neonates with addicted mother

Public title

Investigation and Comparing the effects of foot reflexology and sucrose 24% with pacifier on severity of neonatal Abstinence syndrome among the neonates with addicted mother

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Newborns born with term maternal addiction during pregnancy Get a score of 8 or higher on the Finigan checklist Being hospitalized in educational and medical centers of the place of study Having parental consent

Exclusion criteria:

Having congenital problems, congenital anomalies and injuries during childbirth Having respiratory problems and other problems affecting the symptoms of deprivation

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by block randomization method and based on that, the participants will be placed in one of the intervention and control groups and in a randomized block in terms of material consumed by the mother and Fingan score and type of feeding. Randomization will be performed by a blind staff to study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are blind (blindness is based on the fact that they are infants) and will be intervened in a separate room. It will also be blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University Of Medical Sciences

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Imam Ali Street

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Province

Kerman

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7717933777

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.RUMS.REC.1398.072

Health conditions studied

1

Description of health condition studied

neonatal Abstinence syndrome

ICD-10 code

P96.1

ICD-10 code description

Neonatal withdrawal symptoms from maternal use of drugs of addiction

Primary outcomes

1

Description

on severity of neonatal Abstinence syndrome

Timepoint

Twice a day for 12 hours, before and then 15 minutes and 2 hours after the intervention

Method of measurement

Fingan Tools

Secondary outcomes

1

Description

Number of breaths

Timepoint

Twice a day 12 hours before the intervention, 15 minutes and 2 hours after the intervention

Method of measurement

Counting

2

Description
Heart rate
Timepoint
Twice a day 12 hours before the intervention, 15 minutes and 2 hours after the intervention
Method of measurement
Pulse oximetry device

Intervention groups

1

Description
Intervention group 1: In the sucrose group with pacifier, 2 cc of sucrose solution for infants over 2 kg and 1.5 cc for infants 1.5 to 2 kg and 0.5 cc for infants under 1.5 kg of sucrose 24%(Made by Shahid Ghazi Pharmaceutical Company) Pour a sterile syringe on the front of the baby's tongue, the dose of sucrose was selected based on studies in this field (50) and then put the pacifier in the baby's mouth for 15 minutes. Interventions will be performed twice a day, 12 hours apart. Heart rate was measured using a pulse oximetry device (calibrated and identical), respiration rate was counted, and deprivation syndrome score was measured using the Finigan checklist before the intervention and then 15 minutes and 2 hours after the intervention.
Category
N/A

2

Description
Second intervention group:. In the reflexology group, infants will receive a foot massage (reflexology belief is based on the fact that the foot is a reflection of different organs of the body and foot massage affects different systems). In this intervention, we use zone number one, which is the thumb and toes. We chose that it is directly related to the head and neck and the secretion of endorphins. Reflexology intervention will be performed for 15 minutes. The pressure of the massage is such that the blood supply to the target organ is not disturbed. The basis of Finger Walking is that we first massage the sole of the baby's foot completely, from the heel vertically and walking, with the index finger, and then the desired area will be massaged more. Interventions will be performed twice a day, 12 hours apart. Heart rate using pulse oximetry device (calibrated and identical), number
Category
N/A

3

Description
Control group: The control group will have only the presence of the intervener and the heart rate using the pulse oximetry device (calibrated and identical), the number of breaths counted and the deprivation syndrome score using the Finigan checklist before the intervention and then 15 minutes. And is measured 2 hours after the intervention. Interventions will be performed twice a day, 12 hours apart.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
Rafsanjan 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

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Person responsible for general inquiries

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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

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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