

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of acupuncture and foot reflexology on signs of drug deprivation syndrome among neonatal with addicted mother in the Affiliated medical centers to Rafsanjani University of Medical Sciences, 2017

Protocol summary

Summary

The present study was a randomized, double blind clinical trial with the aim of Comparative study of the effect of acupuncture and foot reflexology on signs of drug deprivation syndrome among neonatal with addicted mother in the affiliated medical centers to Rafsanjan University of Medical Sciences, 2017. The information gathering tool includes a special evaluation tool for infants with symptoms of substance deprivation syndrome called Finnegan. The Inclusion criteria to the study includes Infants born of Addicted mothers who receive at least a score of 8 from the Finnegan tool and need to be admitted to hospital and receive drug treatment. the criteria for the exclusion Neonates born of non-addicted mothers will be considered. In this study, the sample size will be 30 neonates. the Infant will be given twice in the study. So that the first day of admission of the Newborn was randomly assigned to one of the acupuncture by attaching a secure ear at the back of the ear or reflexology in zone 1 Twice a day, 12 hours and one hour before the drug is taken. Two interventions of 12 hours of washout will be considered and the signs of deprivation in the infant before and after intervention will be investigated. Finally, the score of symptoms of withdrawal syndrome will be compared before and after each intervention. In this study, the interventionist. Research researcher and The contributor to the research project as Evaluator will be considered in the research project

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112615965N9**

Registration date: **2017-08-28, 1396/06/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-28, 1396/06/06

Registrant information

Name

Majid Kazemi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.kazemi.n@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Rafsanjan University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of acupuncture and foot

reflexology on signs of drug deprivation syndrome among neonatal with addicted mother in the Affiliated medical centers to Rafsanjani University of Medical Sciences, 2017

Public title

Comparative study of the effect of acupuncture and foot reflexology on signs of drug deprivation syndrome among neonatal

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Neonate with gestational age of at least 37 weeks; Neonate with addicted mother; Neonate with symptoms of drug withdrawal syndrome. Exclusion criteria: Congenital anomalies; Life-threatening conditions; Maternal damage; Parental dissatisfaction with participation in Study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Sciences

Street address

Rafsanjan

City

Rafsanjan

Postal code

7717933777

Approval date

2017-08-02, 1396/05/11

Ethics committee reference number

IR.RUMS.REC.1396.72

Health conditions studied

1

Description of health condition studied

Neonatal abstinence syndrom

ICD-10 code

P96.1

ICD-10 code description

Neonatal withdrawal symptoms from maternal use of drugs of addiction

Primary outcomes

1

Description

Neonatal abstinence syndrom

Timepoint

Twice a day, 12 hours apart

Method of measurement

Finnegan score

Secondary outcomes

empty

Intervention groups

1

Description

The present study is a randomized clinical trial that will be performed on infants born of addicted mothers in affiliated educational and medical centers to Rafsanjan University of Medical Sciences in 2017. Data collection tool includes the special tools for monitoring the infants with drug deprivation syndrome symptoms called finnegan. In this study, each infant will be participated twice in the study. In the first day of admission, the infant was assigned to acupuncture interventions baby twice a day, and every hour before drug treatment by attaching safety earrings called ear-seed on both ears on the mastoid bone at sj17 point for ten minutes will be done.

Category

N/A

2

Description

. Twelve hours after the first intervention (washing time) This will be applied in foot thumb of infants twice daily at intervals of 12 hours, one hour before receiving medical

treatment For ten minutes the signs of deprivation in the infants before and after the intervention using the finnegan tool will be investigated. At the end, the score of the symptoms of the drug deprivation syndrome will be compared before and after each intervention.

Category

N/A

3

Description

control group There is no control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Talib Hospital And NikNafs Maternity Hospital

Full name of responsible person

Dr.Majid Kazemi

Street address

Ali Ibn Abi Talib Square, Imam Ali Street And Shahada Street

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University Of Medical Sciences

Full name of responsible person

Dr.Hamid Hakimi

Street address

Ali Ibn Abi Talib Square, Imam Ali Street and Shahada Street

City

Rafsanjan

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan UniversityOf Medical Sciences

Full name of responsible person

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Position

Master Student Of Nursing

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty