Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the efficiency of methadone and morphine in reducing the Neonatal Abstinence Syndrome born to addicted mothers

Protocol summary

Study aim

The aim of this study was to identify and compare the effectiveness of methadone and morphine in reducing the Neonatal Abstinence Syndrome in infants born to addicted mothers.

Design

A clinical trial with two groups of 50 people treated with morphine or methadone, double-blind in parallel, randomly and indefinitely treated with two drugs.

Settings and conduct

Random and clinical trial of two-blind trial performed in Afzalipour Hospital in Kerman. Study on 100 infants in two groups and a patient with NAS in which patients in both groups were randomly treated with morphine (n = 50) and methadone (n = 50).

Participants/Inclusion and exclusion criteria

The target population of this study is all infants who were born in 2021 in Afzalipour Hospital in Kerman and were admitted to the NICU ward due to Neonatal Abstinence Syndrome (ANS) and are receiving medical treatment and their mother was an opioid user. Inclusion criteria: Infants of mothers who have taken morphine derivatives due to abuse or relief of chronic pain and have been visited at least once or twice for pregnancy care in the third trimester are able to survive. Exclusion criteria: 1. Mothers who consume alcohol 2. Congenital and genetic abnormalities. 3. Taking benzodiazepines during pregnancy 4. Infants who are unable to survive or whose survival is in doubt.

Intervention groups

In the two groups of infants with NAS, a comparison of the duration of hospitalization, the duration of treatment and the side effects of morphine and methadone is performed.

Main outcome variables

Duration of hospitalization Duration of treatment Side effects of the drugs used

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100202003250N7**
Registration date: **2024-10-17, 1403/07/26**
Registration timing: **retrospective**

Last update: **2024-10-17, 1403/07/26**
Update count: **0**

Registration date

2024-10-17, 1403/07/26

Registrant information

Name

Bahareh Bahman Bijari

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the efficiency of methadone and morphine in reducing the Neonatal Abstinence Syndrome born to addicted mothers

Public title
Comparison of the efficiency of methadone and morphine in reducing the Neonatal Abstinence Syndrome born to addicted mothers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Infants of mothers who have taken morphine derivatives due to abuse or relief of chronic pain and have been visited at least once or twice for pregnancy care in the third trimester and are able to survive.

Exclusion criteria:
Mothers who consume alcohol Congenital and genetic abnormalities. Taking benzodiazepines during pregnancy Infants who are unable to survive or whose survival is in doubt.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of the unit is done in a block method with a block size of 4. For each of the 6 possible modes for the block of four, the numbers are assigned as follows, ABBA(3), ABAB(2), AABB(1), BAAB(6), BABA(5), BBAA(4) with the help of the table Random numbers, numbers between 1 and 6 are selected and determined according to each number of the treatment allocation list. To implement the generated random sequence, the method of hiding the box or coded cans is used. In this method, the cans are numbered based on a random sequence, and inside the boxes, the intended intervention (medicine) or a sheet with random allocation written on it, provided that the boxes are completely sealed, is provided to the operator. Based on the order of arrival of the patients, the researcher assigns them to the intervention and standard treatment group. Tools: Creating a random sequence of 4 random blocks, concealment will be done to implement the random sequence on the participants of the study. How to build: random selection of blocks and reading letters from right to left, hiding will be done by the method of cans that are numbered based on a random sequence. The cans have the same weight and shape and will be prepared by an independent researcher.

Blinding (investigator's opinion)
Double blinded

Blinding description
Morphine and methadone are placed in two identical bottles of the same color and appearance, the inside of which is unknown, which the clinical caregiver and the nurse are unaware of the type of drug prescribed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Afzalipour Hospital, Next to Shahid Bahonar University, Imam Khomeini Highway

City
کرمان

Province
Kerman

Postal code
7616913355

Approval date
2021-09-08, 1400/06/17

Ethics committee reference number
IR.KMU.AH.REC.1400.182

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
Duration of hospitalization

Timepoint
Duration of hospitalization

Method of measurement
Therapist's observations

2

Description
Duration of treatment
Timepoint
Duration of hospitalization
Method of measurement
Therapist's observations

3

Description
Side effects of drugs
Timepoint
Duration of hospitalization
Method of measurement
Therapist's observations

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (morphine): In this group, there are 50 patients who are receiving morphine drug treatment. The decision to start drug treatment will be based on the Fingan scoring system. When there is an adequate Fingan standard score (three consecutive Fingan scores greater than 8 or three consecutive Fingan scores greater than 12) for drug treatment, the infant receives the drug under randomized type of drug. In this group, 1 cc of morphine is diluted with 24 cc of distilled water and given to infants. For these infants, the starting dose of treatment will be 0.3-0.2 mg / kg body weight per day divided every 6 hours. The dose of the drug will be evaluated each time based on the score of the Fingan table. If the score of Fingan is higher than 12, the next dose will be added 10% to the dose of the drug, and if the score of Fingan reaches less than 8, the dose of the drug will be reduced again by 10% for the next time. After 48 hours of controlled symptoms (Fingan score between 8 and 12) daily reduced by 10% of the previous maximum dose to below 0.1 mg per kg per day and then morphine will be discontinued. After 48 hours of monitoring, the infant will be discharged.
Category
Treatment - Drugs

2

Description
Intervention group 2 (methadone): There are 50 patients in this group who are receiving methadone drug treatment. The decision to start drug treatment will be based on the Fingan scoring system. When there is an adequate Fingan standard score (three consecutive Fingan scores greater than 8 or three consecutive Fingan scores greater than 12) for drug treatment, the infant receives the drug under study based on a random method of drug type. In this treatment group, the intervention method will be that an oral dose should be given every 6 hours. The starting dose should be 100 µg / kg, each time a higher dose is increased until the symptoms are controlled, increasing to 50 /g / kg every 12 hours. The methadone dose should be reduced by 10 to 20% once a day. After 48 hours of monitoring, the infant will be discharged.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Leila Razi
Street address
Afzalipour Hospital, next to Shahid Bahonar University, Imam Khomeini Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abedin Iranpour
Street address
Vice-Chancellery for Research, Ebn-e-Sina St.,Jahad Blvd. Kerman, Iran
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Postal code
7619813159
Phone
+98 34 3226 3855
Email
iranpourabedin89@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Bahareh Bahman Bijari

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Others

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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available