Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison Bopronorphin and Morphin Among NeonatesWith Obstinence Syndrom Admitted In Birjand Vali-asr Hospital

Protocol summary

Study aim
Determine Mean Duration of Admit Neonate Treated by Morphin and Bupronorphin Compare Mean Duration of Admit Neonate Treated by Morphin and Bupronorphin Determine Relative frequency Complications Apnea and Poor Feeding and Decrease Blood Pressure in Neonate Treated by Morphin and Bupronorphin Compare Relative Frequency Complications Apnea and Poor Feeding and Decrease Blood Pressure in neonate Treated by Morphin and Bupronorphin

Design
Randomized clinical trial in 2 groups 30 neonate treated by morphin or bupronorphin in study of double blind and parallel

Settings and conduct
Randomized clinical double blind trial 60 neonate with Withdrawal Syndrome treated by morphin(30 neonate) or bupronorphin(30 neonate) Admitted In Birjand Vali-asr Hospital

Participants/Inclusion and exclusion criteria
Postnatal Age<7 Days Gestational Age≥ 35 Weeks Prenatal Opium Exposure Symptomatic Patient And 3 Fingan Score ≥8 In 3 Hours Or 2 Fingan Score≥12 No Siezure History No Major Congenital Anomaly No Unstablity In Blood Pressure And Hemodynamic No Major Medical Unstability In Association Of Withdrawal Syndrome No Inclusion Criteria Analgesic Consumption

Intervention groups
Compare Duration of Admit and Complications Morphin and Bupronorphin in 2 Groups of Neonatal Withdrawal Syndrome

Main outcome variables
Duration of Admit and Complications of Routine Drugs

General information

Reason for update

Acronym
BBS

IRCT registration information
IRCT registration number: **IRCT20181231042183N1**
Registration date: **2019-01-18, 1397/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-18, 1397/10/28**
Update count: **0**

Registration date
2019-01-18, 1397/10/28

Registrant information

Name
sepideh Hajmohamadi

Name of organization / entity
The University of Birjand

Country
Iran (Islamic Republic of)

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+98 56 3162 2035

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-07-23, 1398/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison Bopronorphin and Morphin Among NeonatesWith Obstinence Syndrom Admitted In Birjand Vali-asr Hospital

Public title
Assessment Effect of Bopronorphin Neonates With Obstinence Syndrom
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Postnatal Age<7 Days Gestational Age≥ 35 Weeks Prenatal Opium Exposure Symptomatic Patient And 3 Fingan Score ≥8 In 3 Hours Or 2 Fingan Score≥12 No Siezure History No Major Congenital Anomaly No Unstablity In Blood Pressure And Hemodynamic No Major Medical Unstability In Association Of Withdrawal Syndrome
Exclusion criteria:
Analgesic Consumption and withdrawal syndrome
Age
From **1 day** old to **7 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization SingleRandomization Seal Envelop The Hidden Drug in 2 Group of Morphin and Bupronorphin in C and D Solution Randomized Use for Treatment and Nature of Solution is Unclear
Blinding (investigator's opinion)
Double blinded
Blinding description
Morphin and Bupronorphin are in 2Container of C and D with Same Color and Apperance and Stained. All Participant and Researchers and Physician and Nurse and Data Analyser are Unaware of Ordered Drug
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birjand University of Medical Sciences
Street address
Ghafari Ave., Valiasr Hospital
City
Birjand
Province
South Khorasan
Postal code
9717853577
Approval date
2018-10-15, 1397/07/23
Ethics committee reference number
ir.bums.REC.1397.168

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
Admit Duration
Timepoint
Duration of Admit
Method of measurement
Observation of physician

2

Description
Drugs Complications
Timepoint
Admit Duration
Method of measurement
Observation of physician

3

Description
Apnea
Timepoint
Admit Duration
Method of measurement
Observation of physician

4

Description
Feeding
Timepoint
Admit Duration

Method of measurement
Observation of physician

5

Description
Blood Pressure
Timepoint
Admit Duration
Method of measurement
Mercurial Pressure-Gauge Device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Randomized clinical trial study in 60 neonate. 2 group of neonatal abstinence syndrome that randomized divided to 2 group of Buprenorphine (intervention group 30 neonate) and Morphin group (control group 30 neonate).Treat initiation is according to Fingan scoring system. According to enough Fingan scoring medical treatment prescribe. Drugs prescribe is according randomize method. Drugs have same appearance and volume and container and medical group are unexplained about type of drug. A tablet 2 mgr of Bupronorphin (Pharan Shimi® group) dilute in 50 cc water and prescribe in intervention group. Bupronorphin(Intervention group) initiation dose is 0.075 mg/kg/day in 6 divided dose. Drug dose adjust base on number of Fingan score in each assess. If Fingan score be more than 12, the next dose decrease %10 of previous dose. If Fingan score be less than 8, continously drug dose decrease by %10. After each 8 hours of symotoms control (Fingan score 8 to 12), decreasing %10 of maximum dose per day. If minimum dose of drug be under 0.1 mg/kg/day Bupronorphin stop and neonate monitor for each 8 hour and discharge.
Category
Treatment - Drugs

2

Description
Control group: Randomized clinical trial study in 60 neonate. 2 group of neonatal abstinence syndrome that randomized divided to 2 group of Buprenorphine (intervention group 30 neonate) and Morphin group (control group 30 neonate).Treat initiation is according to Fingan scoring system. According to enough Fingan scoring medical treatment prescribe. Drugs prescribe is according randomize method. Drugs have same appearance and volume and container and medical group are unexplained about type of drug. 1 cc Morphin dilute in 24 cc water and prescribe in control group. Morphin (control group) initiation dose is 0.4 mg/kg/day in 6 divided dose. Drug dose adjust base on number of Fingan score in each assess. If Fingan score be more than 12, the next dose decrease %10 of previous dose. If Fingan score be less than 8, continously drug dose decrease by %10. After each 8 hours of symotoms control (Fingan score 8 to 12), decreasing %10 of maximum dose per day. If minimum dose of drug be under 0.1 mg/kg/day Morphin stop and neonate monitor for each 8 hour and discharge.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Gholamreza Faal
Street address
Ghafari Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Toba Kazemi
Street address
Ghafari Ave
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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
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Gholamreza Faal
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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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