

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison Bopronorphin and Morphin Among Neonates With Obstinance 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 $\geq$ 35 Weeks Prenatal Opium Exposure Symptomatic Patient And 3 Fingan Score $\geq$ 8 In 3 Hours Or 2 Fingan Score $\geq$ 12 No Siezure History No Major Congenital Anomaly No Unstablity In Blood Pressure And Hemodynamic No Major Medical Unstablity 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)

Phone

+98 56 3162 2035

Email address

s.hajmohamadi@bums.ac.ir

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 Neonates With Obstinance Syndrom Admitted In Birjand Vali-asr Hospital

Public title

Assessment Effect of Bopronorphin Neonates With
Obstinance 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
Unstability 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 Morphine group (control group 30 neonate). Treat initiation is according to Fingon scoring system. According to enough Fingon 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 Buprenorphine (Pharman Shimi® group) dilute in 50 cc water and prescribe in intervention group. Buprenorphine (Intervention group) initiation dose is 0.075 mg/kg/day in 6 divided dose. Drug dose adjust base on number of Fingon score in each assess. If Fingon score be more than 12, the next dose decrease %10 of previous dose. If Fingon score be less than 8, continuously drug dose decrease by %10. After each 8 hours of symptoms control (Fingon score 8 to 12), decreasing %10 of maximum dose per day. If minimum dose of drug be under 0.1 mg/kg/day Buprenorphine 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 Morphine group (control group 30 neonate). Treat initiation is according to Fingon scoring system. According to enough Fingon 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 Morphine dilute in 24 cc water and prescribe in control group. Morphine (control group) initiation dose is 0.4 mg/kg/day in 6 divided dose. Drug dose adjust base on number of Fingon score in each assess. If Fingon score be more

than 12, the next dose decrease %10 of previous dose. If Fingon score be less than 8, continuously drug dose decrease by %10. After each 8 hours of symptoms control (Fingon score 8 to 12), decreasing %10 of maximum dose per day. If minimum dose of drug be under 0.1 mg/kg/day Morphine 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

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3239 5000

Email

public_r@bums.ac.ir

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

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3239 5000

Email

public_r@bums.ac.ir

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

Pediatrics

Street address

Ghafari Ave

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3239 5000

Email

s.hajmohamadi@bums.ac.ir

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 563239500

Email

s.hajmohamadi@bums.ac.ir

Person responsible for updating data**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

Pediatrics

Street address

Ghafari Ave

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 563239500

Email

S.hajmohamadi@bums.ac.ir

Person responsible for scientific 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

Pediatrics

Street address

Ghafari Ave

City**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