

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of side effects of morphine and fentanyl in infants undergoing mechanical ventilation in the intensive care unit

Protocol summary

Summary

In this double blinded randomized controlled trial we will compare morphine and phentanyl in ventilated neonate. 32 patients with gestational age between 24 to 38 weeks are included. Patients with gestational age more than 24 weeks who need for ventilation will be included in the study after obtaining parents informed consent. Neonates with asphyxia, hyperbilirubinemia, hepatitis and biliary, urinary, cardiac, or gastrointestinal anomalies are excluded from the study. Patients will be divided into two equal groups by closed envelope method. Patients in morphine group will receive a loading dose of 100mcg per hours and maintenance dose of 12mcg per kilogram per hours. Patients in phentanyl group will receive 2mcg phentanyl in one hour intravenously followed by 1.4mcg per kilograms per hours. Two groups will be compared for systemic blood pressure, urinary retention, and drug side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105216532N1**
Registration date: **2012-09-18, 1391/06/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-18, 1391/06/28

Registrant information

Name

Salma Naderi

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 76 1666 6240

Email address

snaderi@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2012-08-20, 1391/05/30

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of side effects of morphine and fentanyl in infants undergoing mechanical ventilation in the intensive care unit

Public title

Analgesic effects of opiates on neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Gestational age more than 24 weeks; Need for ventilation because of respiratory distress; Parents informed consent
Exclusion criteria: Asphyxia; Hyperbilirubinemia; neonatal hepatitis; Biliary duct anomalies; Urinary system anomalies; cardiac anomalies; gastrointestinal obstruction

Age

From **1 year** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hormozgan University of Medical Sciences

Street address

Shahid Mohammadi Hospital

City

Bandar Abbas

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

HEC-9-5-2

Health conditions studied

1

Description of health condition studied

Respiratory Distress Syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Systolic Blood Pressure

Timepoint

Baseline, 2nd day

Method of measurement

Mercury barometer

Secondary outcomes

1

Description

Urinary retention

Timepoint

Baseline, 2nd Day

Method of measurement

Diagnosed by specialist

Intervention groups

1

Description

100mcg per kilograms morphine in 1 hours followed by 12 mcg per kilograms per hours intravenous morphine

Category

Treatment - Drugs

2

Description

2 mcg phentanyl per kilogram followed by 1.4 mcg per kilogram per hours intravenously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Koodakan hospital

Full name of responsible person

Dr Salma Naderi

Street address

Koodakan Hospital, Golshahr

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Dr Azim Nejatizadeh

Street address

Koodakan hospital

City

Bandar Abbas

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Hormozgan 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

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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