

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

**Contact**  
**Name of organization / entity**  
Hormozgan University of Medical Sciences  
**Full name of responsible person**  
Dr Salma Naderi  
**Position**  
Neonatologist  
**Other areas of specialty/work**  
**Street address**  
Koodakan Hospital, Golshahr  
**City**  
Bandar Abbas  
**Postal code**  
**Phone**  
+98 76 1333 7192  
**Fax**  
**Email**  
salmanaderi@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Hormozgan University of Medical Sciences  
**Full name of responsible person**  
Dr Salma Naderi  
**Position**  
Neonatologist  
**Other areas of specialty/work**  
**Street address**

Koodakan Hospital, Golshahr  
**City**  
Bandar Abbas  
**Postal code**  
**Phone**  
+98 76 1333 7192  
**Fax**  
**Email**  
salmanaderi@gmail.com  
**Web page address**

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Hormozgan University of Medical Sciences  
**Full name of responsible person**  
Dr Salma Naderi  
**Position**  
Neonatologist  
**Other areas of specialty/work**  
**Street address**  
Koodakan Hospital  
**City**  
Bandarabbas  
**Postal code**  
**Phone**  
+98 76 1333 3280  
**Fax**  
**Email**  
**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*