

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparing the Effect of Different Doses of Fentanyl on Sedation of Infants with respiratory distress syndrome under Mechanical Ventilation; A Randomized Clinical Trial

Protocol summary

Summary

This randomized clinical trial was conducted to compare the effect of two different doses of Fentanyl on sedation of 60 infants with respiratory distress syndrome between 2.5 and 4 kg of weight who needed mechanical ventilation. Patients lower than 2.5 kg and more than 4 kg, as well as those with congenital heart disease, brain anomalies and metabolic or chromosomal syndromes were excluded from the trial. Patients were randomly allocated to two groups; the first group underwent sedation with Fentanyl (0.5 mcg/kg) and the second group received 1 mcg/kg of Fentanyl during ventilation. Sedative effects of drugs were evaluated by respiratory rate, arterial oxygen saturation and concentration of required oxygen. Duration of hospitalization, required time of ventilation were recorded and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082517413N27**

Registration date: **2017-11-17, 1396/08/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-17, 1396/08/26

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2016-06-01, 1395/03/12

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Different Doses of Fentanyl on Sedation of Infants with respiratory distress syndrome under Mechanical Ventilation; A Randomized Clinical Trial

Public title

The effect of two different doses of Fentanyl on sedation of infants with respiratory distress syndrome under mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infants between 2.5 and 4 kg of weight with respiratory distress syndrome who needed intubation and mechanical ventilation
Exclusion criteria: Patients lower than 2.5 kg and more than 4 kg;

congenital heart disease; brain anomalies; metabolic or chromosomal syndromes

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization was done using random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Pharmaceutical Sciences Branch, Islamic Azad University

Street address
Yasaman alley, Yakhchal st. ,Tehran

City
Tehran

Postal code

Approval date
2015-09-09, 1394/06/18

Ethics committee reference number
IR.IAU.PS.REC.1395.28

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrome of newborn

ICD-10 code
P22.0

ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Respiratory rate

Timepoint
before and one hour after intervention

Method of measurement
Respiration count in one minute by nurse

2

Description
Arterial Oxygen saturation

Timepoint
before and one hour after intervention

Method of measurement
Pulse Oxymetry

3

Description
Duration of hospitalization

Timepoint
Beginning of study to discharge

Method of measurement
Counting hospital stay days

4

Description
Duration of Ventilation

Timepoint
After Intervention

Method of measurement
Counting ventilator-dependent days

5

Description
Oxygen concentration

Timepoint
before and one hour after intervention

Method of measurement
Mechanical ventilation device

Secondary outcomes

1

Description
Pneumothorax

Timepoint
After Intervention

Method of measurement
Plain chest X-ray

Intervention groups

1

Description
First group: Fentanyl 0.5 mcg/kg as single dose

Category

Treatment - Drugs

2

Description

Second group: Fentanyl 1 mcg/kg as single dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Najmīyeh Hospital

Full name of responsible person

Bitā Najafian

Street address

Hafez, Jomhouri st., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Baqiyatallah University of Medical Sciences

Full name of responsible person

Morteza Izadi

Street address

Baqiyatallah University of Medical Sciences, Nosrati Alley, Sheykh Bahaei st., Mollasadra st., Vanaq sq.,

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Baqiyatallah 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

Student Research Committee, Baqiyatallah University of Medical Sciences, Tehran, Iran

Full name of responsible person

Mohammad Hossein Khosravi

Position

Secretary-General

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Neonatologist

Other areas of specialty/work

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Person responsible for updating data

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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