

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

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Neonatologist

Other areas of specialty/work

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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