

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of Fentanyl and Midazolam on the Sedation of infants under mechanical ventilation; A Randomized Clinical Trial

Protocol summary

Summary

This randomized clinical trial was conducted to compare the effect of Midazolam and Fentanyl on sedation of 60 infants 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 Midazolam (0.1 mg/kg) and the second group received 0.5mcg/kg of Fentanyl during ventilation. Duration of hospitalization, required time of ventilation, drug complications and feeding intolerance were recorded and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082417413N26**

Registration date: **2017-09-02, 1396/06/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-02, 1396/06/11

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

2016-07-01, 1395/04/11

Expected recruitment end date

2017-03-03, 1395/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Fentanyl and Midazolam on the Sedation of infants under mechanical ventilation; A Randomized Clinical Trial

Public title

Comparison of Midazolam and Fentanyl for sedation of infants under mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infants between 2.5 and 4 kg of weight 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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Pharmaceutical Sciences Branch,
Islamic Azad University

Street address

Pharmaceutical Sciences Branch, Islamic Azad
University, Yasaman Alley, Yakhchal Street, Tehran,
Iran

City

Tehran

Postal code

Approval date

2015-09-09, 1394/06/18

Ethics committee reference number

IR.IAU.PS.REC.1394.14

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

Duration of hospitalization

Timepoint

After Intervention

Method of measurement

Counting hospital stay days

2

Description

Duration of Ventilation

Timepoint

After Intervention

Method of measurement

Counting ventilator-dependent days

Secondary outcomes

1

Description

Pneumothorax

Timepoint

After Intervention

Method of measurement

Plain chest X-ray

Intervention groups

1

Description

Second group: Fentanyl 0.5 mcg/kg

Category

Treatment - Drugs

2

Description

First group: Midazolam 0.1 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Najmiyeh Hospital

Full name of responsible person

Bitra 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
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 Secretary-General
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Person responsible for scientific inquiries

Contact

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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