

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effectiveness of fentanyl with placebo on pain relief during endotracheal suctioning in ventilated children

Protocol summary

Study aim

Determining the efficacy of fentanyl on pain resulting from endotracheal suction in mechanically ventilated patient in the PICU

Design

Two arm parallel group, randomized, double blinded, phase 2 on 50 patients. Randomization with odd or even number of the bed of admission.

Settings and conduct

The study was performed in pediatric intensive care units in the Emam Hosein children hospital in 2020, Isfahan, Iran. Demographic data of all patients including age, gender, reason of admission and mechanical ventilation duration were collected. We measured pain with FLACC scale and physiologic indices (heart rate and systolic and diastolic arterial pressure, respiratory rate, and oxygenation saturation) by the time of endotracheal suctioning. Patients were randomly divided into 2 groups receiving 1 µg/kg fentanyl or normal saline as placebo. The drugs were administered before endotracheal suctioning and the pain score and physiologic indices changes were evaluated. Participants, main researcher, doctors and nurses were blinded in this study. The data gathering and analyses were not blinded. Drugs were numbered by the pediatric resident in 2 cc syringes with the same volume and dilution percentage. The nurse who was not aware of the type of injectable product.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged two months to 12 years under mechanical ventilation; signing the written informed by the parents to participate. Exclusion criteria: history of any neuromuscular disorders; diagnosis of acute respiratory distress syndrome (ARDS); treatments with muscle relaxants; treatment with another analgesic drug an hour before the intervention.

Intervention groups

in control group injection of 1µg/kg fentanyl diluted up to 2 cc and in placebo group injection of 2 cc normal saline

Main outcome variables

Pain was measured with behavioral scale and vital sign variability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210408050902N1**

Registration date: **2021-11-22, 1400/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-22, 1400/09/01**

Update count: **0**

Registration date

2021-11-22, 1400/09/01

Registrant information

Name

Sharareh Babaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3275 0621

Email address

sharareh.babaie@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of fentanyl with placebo on pain relief during endotracheal suctioning in ventilated children

Public title

Effect of fentanyl on pain during endotracheal suctioning in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children aged two months to 12 years under mechanical ventilation Signing the written informed by the parents to participate in this study

Exclusion criteria:

History of any neuromuscular disorders Diagnosis of acute respiratory distress syndrome (ARDS) Treatments with muscle relaxants Treatment with another analgesic drug an hour before the intervention

Age

From **2 months** old to **12 months** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random numbers tool according to new admission on odd numbers or even numbers of the bed

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, main researcher, doctors and nurses were blinded in this study. The data gathering and analyses were not blinded. Drugs were numbered by the pediatric resident in 2 cc syringes with the same volume and dilution percentage and placed in the ward daily. The nurse who was not aware of the type of injectable product.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Esfahan University of Medical Sciences

Street address

Hezar Jerib Ave., Isfahan University of Medical Sciences

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-03-06, 1399/12/16

Ethics committee reference number

IR.MUI.MED.REC.1399.1106

Health conditions studied**1****Description of health condition studied**

Neurologic disorders

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Respiratory diseases

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Infectious diseases

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

Metabolic diseases

ICD-10 code**ICD-10 code description****5****Description of health condition studied**

Renal diseases

ICD-10 code**ICD-10 code description****6****Description of health condition studied**

Hematologic diseases

ICD-10 code
ICD-10 code description

7

Description of health condition studied

GI diseases

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Before and after endotracheal suction

Method of measurement

FLACC behavioral scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: fentanyl with dose one micro-gram per kilogram diluted up to 2 cc before endotracheal suction slow intravenous injection

Category

Treatment - Drugs

2

Description

Control group: Intervention group: 2 cc Normal Salin before endotracheal suction slow intravenous injection

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein children hospital

Full name of responsible person

Sharareh Babaie

Street address

Emam Khomeini street

City

Esfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 6266

Email

emamhossein_hospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Azadi square

City

Esfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3793 2234

Email

international@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Sharareh Babaie

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Emam Khomeini street

City

Esfahan

Province

Isfahan

Postal code

8158856311

Phone

+98 31 3275 0621

Email

sharareh.ba@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Sharareh Babaie

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Imam Hosein hospital, Imam Khomeini avenue

City

Esfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 6266

Email

sharareh.ba@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Sharareh Babaie

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Imam Hosein hospital, Imam Khomeini avenue

City

Esfahan

Province

Isfahan

Postal code

8195163381

Phone

0098 31 333866266

Email

Sharareh.ba@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

share all of the participant personal data

When the data will become available and for how long

access instantly after publication

To whom data/document is available

Researcher works in academic and scientific institutions

Under which criteria data/document could be used

Use the data for similar study with any kind of analysis is allowed

From where data/document is obtainable

authors E-Mail address

What processes are involved for a request to access data/document

Applying with E-Mail then the data will be send within two weeks

Comments