

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Venous Fentanyl on Reducing the Pain of Lumbar Puncture in Neonates

Protocol summary

Summary

The purpose of this study is to assess the efficacy and safety of intravenous fentanyl on reducing the pain of lumbar puncture in neonates. This study will be conducted on 46 neonates admitted to NICU of Shahid Sadoughi hospital for whom lumbar puncture is performed for the first time. Infants with neuromuscular disorders and those with consumption of sedatives or hypnotics during 12 hours before the study, will be excluded from the study. The neonates will be randomly allocated in two groups. In one group 2mcg/kg of intravenous fentanyl diluted to 0.2 ml with N/S will be injected intravenously. In the second group 0.2ml N/S will be administered as placebo. In both groups, fentanyl or placebo will be injected 5 min before lumbar puncture. O2 saturation and PR will be recorded before and during injection of fentanyl every 2 min until 10 min. Pain score and side effects will be evaluated and compared between two groups when needle inserts the skin for lumbar puncture.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014022616761N1**

Registration date: **2014-04-16, 1393/01/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-16, 1393/01/27

Registrant information

Name

Samane Habibian

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 2425 1798

Email address

dr.habibian1@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Venous Fentanyl on Reducing the Pain of Lumbar Puncture in Neonates

Public title

Effect of Fentanyl on Pain Reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age > 34 weeks ; neonates hospitalized in NICU; Weight >1800gr; neonates who need lumbar puncture according to clinical judgment
Exclusion criteria: age >2 months; neuromuscular disorders; use of sedative or hypnotic drugs 12 hours before LP; low level of consciousness

Age

From **1 day** old to **2 months** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi Univercity of Medical Sciences

Street address

Bahonar Square

City

Yazd

Postal code

۸۹۱۵۸۴۵۳۵۴

Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

۱۷/۱/۲۵۷۴۲۸/پ

Health conditions studied

1

Description of health condition studied

Diseases of central nervous system

ICD-10 code

G99

ICD-10 code description

Other disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description

Pain reduction and obtaining pain score of 3 and less

Timepoint

When needle inserts the skin

Method of measurement

observation

2

Description

Succeful lumbar puncture

Timepoint

When lumbar puncture to complete

Method of measurement

Observe

Secondary outcomes

1

Description

Side effects

Timepoint

30 min after drug usage

Method of measurement

Clinical exam and monitoring

Intervention groups

1

Description

Intervention group: Single dose of intravenous fentanyl; manufactured by Caspianamin pharmaceutical Co. Iran; 2 mcg/kg diluted to 0.2 ml with normal saline

Category

Treatment - Other

2

Description

control group:single dose of normal saline 0.2ml;manufactured by Samen pharmaceutical Co. Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital-NICU

Full name of responsible person

Dr.Samane Habibian

Street address

Shahid Sadoughi Hospital,Ebnesina Avenue,Shahid Ghandi Avenue

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research-Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr.Fateme Ezodinee

Street address

University central building,Bahonar Square

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of research-Shahid Sadoughi 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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr.Samane Habibian

Position

Resident

Other areas of specialty/work

Street address

Shahid Sadoughi hospital-Pediatric ward

City

Yazd

Postal code

8975116575

Phone

+98 35 2425 1798

Fax

+98 35 2422 3701

Email

dr.habibian1@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr.Mahmood Noori Shadkam

Position

Neonatologist

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital-NICU

City

Yazd

Postal code

8915845354

Phone

+98 35 1811 3276

Fax

+98 35 1822 4100

Email

Noorishadkam@ssu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of medical Sciences

Full name of responsible person

Dr.Samane Habibian

Position

Resident

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital-pediatric ward

City

Yazd

Postal code

8975116575

Phone

+98 35 2425 1798

Fax

+98 35 2422 3701

Email

dr.habibian1@ssu.ac.ir

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