

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of Pethidine administration on feeding behavior and physiological parameters in newborns delivered by cesarean with spinal anesthesia

Protocol summary

Summary

The aim of this study is the effect of Pethidine administration on feeding behavior and physiological parameters in newborns delivered by cesarean with spinal anesthesia. This study is a randomized clinical trial on 116 pregnant women undergoing non-emergency cases admitted to Gerash-Iran hospital will be done. The main condition Inclusion is mother's wish to breastfeed her infant and the main conditions excluded is birth weight infants too little or too much weight, and low Apgar score. At first, the researcher's assistance educates the standard breastfeeding method for all mothers who have been admitted to study. After the spinal anesthesia and the end of the cesarean section in the intervention group, a single dose of 100 mg of pethidine is given by the anesthesiologist. In the control group, routine care (diclofenac suppository 100 mg) will be performed. With the onset of breastfeeding, researcher and research assistant record feeding behavior and physiologic parameters in two groups and will continue until 48 hours later. Variables include the feeding behavior, arterial PO₂, heart rate, respiratory rate, and temperature of infants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042233163N2**
Registration date: **2017-08-14, 1396/05/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

Name

zohre montaseri

Name of organization / entity

Shiraz University of Medical Science

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Phone

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montaseriz@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences

Expected recruitment start date

2017-07-11, 1396/04/20

Expected recruitment end date

2017-10-12, 1396/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Pethidine administration on feeding behavior and physiological parameters in newborns delivered by cesarean with spinal anesthesia

Public title

Pethidine effect on feeding behavior and physiological parameters of the infant

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: mothers of childbearing age; The candidates are non-emergency cases; gestational age between 38 to 42 weeks; singleton pregnancy; tend to breastfeeding 6-ASAI (Anesthesia class specified by the Anesthesiologist); No history of mental illness and depression; Would like to participate in the study. Exclusion criteria: birth weight less than 2500 and more than 4,000 grams; First or fifth minute Apgar score less than seven; Meconium-stained amniotic fluid; Any abnormalities in the infant; using contraindicated drugs during breastfeeding; Formula feeding or bottle feeding; reluctant mother to continue to participate in the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz University Of Medical Sciences, Zand Avenue, Shiraz, Iran

City

Shiraz

Postal code

1433671348

Approval date

2017-07-09, 1396/04/18

Ethics committee reference number

IR.SUMS.REC.1396.65

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

The effect of Pethidine administration on feeding behavior and physiological parameters in newborns delivered by cesarean with spinal anesthesia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Feeding behavior

Timepoint

Three months after the start of the study

Method of measurement

Infant Breastfeeding Assessment Tool (IBAT)

Secondary outcomes**1****Description**

Oxygen saturation

Timepoint

Three months after the start of the study

Method of measurement

Pulse oximeter

2**Description**

Pulse rate

Timepoint

Three months after the start of the study

Method of measurement

Pulse oximeter

3**Description**

Breathing

Timepoint

Three months after the start of the study

Method of measurement

Observation

4**Description**

Body temperature

Timepoint

Three months after the start of the study

Method of measurement

Digital thermometer

Intervention groups

1

Description

Intervention group: administration of 100 mg of pithidine intravenous infusion after the Cesaren section

Category

Treatment - Drugs

2

Description

Control group: In this group was not given any narcotic drug. And non-opioid drugs such as diclofenac suppository is used to control pain.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-al Momenin hospital, Gerash

Full name of responsible person

Mrs. Ahmadi

Street address

Amir-al Momenin hospital, sheibani street, Gerash, Iran

City

Gerash

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Hatam Gholamreza

Street address

Shiraz University Of Medical Sciences, Zand St.

City

Shiraz

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, Shiraz 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

Shiraz University of Medical Science, Shiraz Hazrate Fatemeh Nursing and Midwifery college

Full name of responsible person

Montaseri Zohreh

Position

Master of Pediatric Nursing, Nursing Trainer

Other areas of specialty/work

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Position

Neonatal Intensive Care Nursing Student

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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