

# 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 PO<sub>2</sub>, 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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Iran (Islamic Republic of)

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#### 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**

**Street address**

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**Position**

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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*