

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between pethidine & fentanyl effects in painless normal vaginal delivery.

Protocol summary

Summary

Objectives One reason for higher tendency to cesarean delivery is delivery pain. If delivery pain don't relieved may cause maternal psychosocial health problems that impair maternal-neonatal relation and postpartum depression. The aim of this study is to compare intravenous fentanyl and intramuscular pethidine effects in pain control, as well as their side effects to find a suitable medication for delivery pain relieving and decreasing of C-section and prevention of its undesirable consequences. **Design** This study is a not blinded clinical trial and patients after informed consent for participation in the study was divided into two groups. **Setting and conduct** All subjects who have inclusion criteria were randomly divided in two groups (30 patients in each group) and therapeutic interventions performed on them. **Participants** including major eligibility criteria, Sixty women who referred for normal vaginal delivery in the first stage of labor (cervical dilatation of 4 cm to 10 cm) enrolled in study. **Inclusion criteria** are one fetus pregnancy; cephalic presentation; multiparty; GA: 38-40 wks; trend to painless delivery; patient Blood pressure>90 & heart rate>60; age 18-40 yr. **Exclusion criteria** including allergy to opium; drug abuse; Wt<50kg & Wt>100kg; high risk pregnancy: preeclampsia, severe asthma, insulin dependent diabetes, Cardiovascular disease, myasthenia gravis, epilepsy, liver and kidney diseases. **Intervention** First group receive 50 to 100 mcg per hour fentanyl as IV and second group pethidine 50 mg intramuscular for pain relieving which can repeated every 1 to 2 hours up to 100 mg. **Vital signs** monitor and record every 30 minutes and the patient is monitored with a pulse oximeter. If the mother need to a c-section for any reason and her breathing rate is less than 8/min and heart rate less than 50/min and O2 saturation less than 90% for more than 15 seconds and don't recovered by oxygen therapy, these conditions considered as severe complications, the drugs discontinued and the patient exclude from study. Also, if delivery takes place

during 1 hour after injection the patient will exclude. The prescribed procedures, control of vital signs and determining of pain score evaluate by resident and only anesthesia team will aware from the type of prescribed drugs. **Main outcome measures (variables)** Intense of pain evaluate before and after drug administration. 2 hours after delivery patient satisfaction assessed and recorded by 0-10 score. **Occurrence of symptoms** including nausea, vomiting and itching, newborn Apgar score in first and fifth minutes, the need to naloxan and oxygen in newborn will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120811504N3**

Registration date: **2013-07-16, 1392/04/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-16, 1392/04/25

Registrant information

Name

Sanam Moradan

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Semnan University of

Medical Sciences	
Expected recruitment start date 2012-12-08, 1391/09/18	1
Expected recruitment end date 2014-03-20, 1392/12/29	Ethics committee
Actual recruitment start date empty	Name of ethics committee Ethics Committee Of Semnan university of Medical Sciences
Actual recruitment end date empty	Street address Basij Boulevard, In front of governor
Trial completion date empty	City Semnan
Scientific title Comparison between pethidine & fentanyl effects in painless normal vaginal delivery.	Postal code 3519747167
Public title Randomized comparison of intramuscular pethidine and intravenous fentanyl for pain relief during first stage of labor and their side effects.	Approval date 2012-04-29, 1391/02/10
Purpose Treatment	Ethics committee reference number 1234
Inclusion/Exclusion criteria Inclusion criteria: one fetus pregnancy; cephalic presentation; multiparity; GA:38-40wks; trend to painless delivery; patient Blood pressure>90 and heart rate > 60; AGE 18-40 yr. Exclusion criteria: allergy to opium; drug abuse; Wt< 50kg and Wt > 100 kg; high risk pregnancy: preeclampsia, severe asthma, insulin dependent diabetes, cardiovascular disease, Myasthenia gravis, epilepsy, liver and kidney disease.	Health conditions studied
Age From 18 years old to 40 years old	1
Gender Female	Description of health condition studied Analgesia in Normal Vaginal Delivery
Phase 2-3	ICD-10 code O80
Groups that have been masked No information	ICD-10 code description cases with minimal or no assistance, with or without episiotomy delivery in a completely normal case
Sample size Target sample size: 60	Primary outcomes
Randomization (investigator's opinion) Randomized	1
Randomization description	Description Labor pain
Blinding (investigator's opinion) Not blinded	Timepoint q 15min after first drug injection
Blinding description	Method of measurement vas(pain score)
Placebo Not used	2
Assignment Parallel	Description Drug
Other design features	Timepoint q1hour
Secondary Ids empty	Method of measurement mili litr
Ethics committees	3
	Description Age
	Timepoint 18 -40
	Method of measurement year
	Secondary outcomes

1

Description

Nausea & vomiting

Timepoint

q15min

Method of measurement

observer detection

2

Description

FHR

Timepoint

q 15 min

Method of measurement

observer detection

3

Description

Apgar

Timepoint

q 15 min

Method of measurement

observer detection

Intervention groups

1

Description

Pethidin 50 mg IM, repeat q 1-2 hr if needed, maximum dose 100 mg

Category

Treatment - Drugs

2

Description

Phentanol 50-100 microgram in hr / IV repeat q 1-2 hr if needed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital

Full name of responsible person

Mojdeh Namdari

Street address

Amir Al Momenin Hospital, Imam Hussein Square

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Semnan University of Medical Sciences

Full name of responsible person

Raheb Ghorbani

Street address

Vice Chancellor for Research of Semnan University of Medical Sciences, Basij Bulvar

City

Semnan

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 of Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mojdeh Namdar

Position

Resident of Gynecology

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Mozhdeh Namdari

Position

Resident of Gynecology

Other areas of specialty/work