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 than15 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

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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
Expected recruitment end date
2014-03-20, 1392/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
Randomized comparison of intramuscular pethidine and intravenous fentanyl for pain relief during first stage of labor and their side effects.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: one fetus pregnancy; cephalic presentation; multiparty; 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.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Semnan university of Medical Sciences
Street address
Basij Boulvard, In front of governor
City
Semnan
Postal code
3519747167
Approval date
2012-04-29, 1391/02/10
Ethics committee reference number
1234

Health conditions studied

1

Description of health condition studied
Analgesia in Normal Vaginal Delivery
ICD-10 code
O80
ICD-10 code description
cases with minimal or no assistance, with or without episiotomy delivery in a completely normal case

Primary outcomes

1

Description
Labor pain
Timepoint
q 15min after first drug injection
Method of measurement
vas(pain score)

2

Description
Drug
Timepoint
q1hour
Method of measurement
mili litr

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
Phentanil 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 Bulvard
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

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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