

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of adding Remifentanyl to Entonox in reducing labour pain in first stage of active phase of labour in parturients

Protocol summary

Summary

30 parturients were participated in a double blinded, cross-over study. The patients were eligible for the study ,if they have singleton ASA1 pregnancies without complication such as pre eclampsia and if the fetus was in a normal cephalic presentation. patients were recruited during the active phase of labour when cervical dilatation was about 4-8 cm . the patients who were opium abuser, cigarette smoker or had history of chronic NSAIDS or analgesic drugs use, were excluded. After randomization the selected patients received the study medicines during two 30-min study periods with a 15-min wash-out sequence after each period.15 patients used remifentanyl and Entonox during the first period and entonox and sodium chloride 0.9% during the second while the reminder of the patients used the drugs in a reverse order. Intravenous remifentanyl with the loading dose of 0.25µg/kg and 0.025 µg/kg/min infusion from 0/5µg/cc solution for 30 minutes were used in this study, and 15 minutes lock-out intervals was given to them and then sodium chloride 0.9% is infused with the same rate for 30 minutes. During the period of intravenous infusion , inhalant enthonox is used by parturients. The severity of uterine pain after each contraction, heart rate/ blood pressure, oxyhemoglobuline saturation and fetal heart rate were assessed every 5 minutes in parturients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104026115N1**

Registration date: **2012-08-14, 1391/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-14, 1391/05/24

Registrant information

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Name of organization / entity

Esfahan medical university

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding Remifentanyl to Entonox in reducing labour pain in first stage of active phase of labour in parturients

Public title

The effect of adding Remifentanyl to Entonox in reducing labour pain in first stage of active phase of labour in parturients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: samples are taken from the ASA1 term parturients: cephalic presentation who are in the active phase of labor (dilation 4-8 cm) and natural delivery. Exclusion criteria: patients who do not have one of the interventional periods for any reasons (remifentanyl and entonox): have got serious complications that result cesarean section: NSAIDs and cigarette users.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan Medical University

Street address

Hezar jerib street, Isfahan University of Medical Sciences, Daneshgah Ave.

City

Isfahan

Postal code

Approval date

2010-10-25, 1389/08/03

Ethics committee reference number

189057

Health conditions studied

1

Description of health condition studied

labour pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Labour pain

Timepoint

before intervention and after each contraction

Method of measurement

VAS

Secondary outcomes

1

Description

Sedation

Timepoint

Before and after intervention

Method of measurement

RAMSEY Score

2

Description

Nausea

Timepoint

Before and after intervention

Method of measurement

VAS

Intervention groups

1

Description

Intervention group: intravenous remifentanyl (ultra short acting potent opioid) with the loading dose of 0.25µg/kg and 0.025 µg/kg/min infusion from 0/5µg/cc solution for 30 minutes were used and inhaled entonox in each contraction

Category

Treatment - Drugs

2

Description

Control group: Sodium chloride 0.9% is infused with the same rate for 30 minutes. During the each period of intravenous infusion , and inhaled entonox in each contraction

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaid Beheshti Hospital

Full name of responsible person

Naghmeh Ahmadi
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Motahary street, Pol Felezy, Esfahan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellery for Research Isfahan University of Medical Sciences.
Full name of responsible person
Dr Peiman Adibi
Street address
Hezar jerib street, Esfahan, Esfahan university of medical sciences
City
Isfahan

Grant name
189057

Grant code / Reference number
189057

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

Title of funding source
Vice-Chancellery for Research Isfahan 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

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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