Comparison of Incremental Bolus and Infusion Administration of Remifentanil on Labor Pain and Length of Delivery Time in Women During Labor.

Protocol summary

Summary
Remifentanil is one of drugs for controlling labor pain. Despite numerous studies, researchers have not reached a consensus at the method and dose of remifentanil administration. In this study, we will compare two different methods of remifentanil administration (incremental bolus and incremental infusion) in controlling labor pain and the effect on length of labor in the stage I and II. The aim of this study is to find an appropriate method to relieve labor pain which has maximum analgesic effect in minimum dose and not to make labor prolong. In this randomized, single-blind clinical trial, 82 primigravid pregnant women, with gestational age of 37-42 weeks and dilation ≥3 cm or more, are randomly assigned in two groups of 41. Remifentanil is administered by bolus for one group and in continuous infusion for another group. Pain severity, whole dose of remifentanil administration in each patient, the duration of labor, and the newborn Apgar scores will be compared in these two groups.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2012100811020N2
Registration date: 2013-02-18, 1391/11/30
Registration timing: registered_while_recruiting

Email address
khooshide@tums.ac.ir

Recruitment status
Recruitment complete

Funding source
Zahedan University of Medical Sciences

Expected recruitment start date
2012-01-23, 1390/11/03

Expected recruitment end date
2013-03-19, 1391/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Incremental Bolus and Infusion Administration of Remifentanil on Labor Pain and Length of Delivery Time in Women During Labor.

Public title
Effect of different methods of remifentanil administration in labor pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: primigravid healthy parturient with 37-42 weeks of pregnancy; in active stage of labor (uterine contraction 3 per 10 minutes, lasting for 30 to 40 seconds and cervical dilation ≥3 cm); with vertex presentation. Exclusion criteria: parturient with positive history of preeclampsia; using psychiatric drugs; using opioid and alcohol; antenatal hemorrhage; fetal distress; BMI>30 or <20; multi tone and requesting for epidural analgesia.

Age
From 18 years old to 35 years old

Gender
Female

Phase
N/A
Groups that have been masked
None

Sample size
Target sample size: 82

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Zahedan University of Medical Sciences

Street address
Vice chancellor for research, Zahedan University of Medical Sciences, Dr Hesabi Sq.

City
Zahedan

Country
Iran (Islamic Republic of)

Postal code

Approval date
2010-11-07, 1389/08/16

Ethics committee reference number
87-1804

Health conditions studied

1

Description of health condition studied
Single spontaneous delivery

ICD-10 code
O80

ICD-10 code description
cases with minimal or no assistance, with or without episiotomy

Primary outcomes

1

Description
severity of uterine contractions pain

Timepoint
Every 15 minutes from the onset of active phase of labor to delivery

Method of measurement
verbal numeric rating scale (VNRS)

2

Description
first stage of labour duration

Timepoint
every 15 minutes in first stage of labour from 4 cm dilation up to 10 cm, and in second stage from 10 cm dilation up to delivery.

Method of measurement
Time by minutes

Secondary outcomes

1

Description
grading of sedation

Timepoint
every 15 minutes

Method of measurement
Modified Observer’s Assessment of Alertness

Intervention groups

1

Description
If the intensity of pain reaches to 7 or more (based on verbal numeric grading criteria) in group A, remifentanil (in method of incremental infusion) will be prescribed from 0.025 microgram per kg of body weight of the patients in minute and if needed its dose gradually increases to 0.05, 0.075, and 0.1. For preparing, 1 mg remifentanili is diluted into 100 ml of normal saline in solution (concentration of 10 micrograms per milliliter).

Category
Treatment - Drugs

2

Description
If the intensity of pain reaches to 7 or more (based on verbal numeric grading criteria) in group B, remifentanil (in method of incremental bolus) will be prescribed in dose of 0.25 microgram per kg, and if needed another bolus will be received in dose of 0.5 microgram per kg. Lockout time between two boluses was 4 minutes. For preparing, 1 mg remifentanili is diluted into 100 ml of normal saline in solution (concentration of 10 micrograms).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center  
Ali Ebn Abitaleb Hospital

Full name of responsible person
Street address
City
Zahedan
Country
Iran (Islamic Republic of)

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences, Deputy of Research

Full name of responsible person
Dr. Hamidreza Mahmoodzade-sagheb

Street address
Deputy of Research, University of Medical Sciences, Dr hesabi Sq.,

City
Zahedan

Country
Iran (Islamic Republic of)

Grant name

Grant code / Reference number

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

Title of funding source
Zahedan University of Medical Sciences, Deputy of Research

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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Maryam Khooshide

Position
specialist in obstetrics and gynecology

Other areas of specialty/work

Street address
Arash women's hospital, Baghdarnia avenue, shahid bagheri highway, Resalat highway, Tehranpars

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Person responsible for scientific inquiries

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specialist in obstetrics and gynecology

Other areas of specialty/work

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Fax
Email

Web page address

Person responsible for updating data

Contact

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