

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

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

Protocol summary

Summary

Remifentanyl is one of drugs for controlling labor pain. Despite numerous studies, researchers have not reached a consensus at the method and dose of remifentanyl administration. In this study, we will compare two different methods of remifentanyl 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. Remifentanyl is administered by bolus for one group and in continuous infusion for another group. Pain severity, whole dose of remifentanyl 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**

Last update:

Update count: **0**

Registration date

2013-02-18, 1391/11/30

Registrant information

Name

Maryam Khoshideh

Name of organization / entity

Tehran University of Medical Sciences, Arash Hospital

Country

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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 Remifentanyl on Labor Pain and Length of Delivery Time in Women During Labor.

Public title

Effect of different methods of remifentanyl 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

No information

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

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, remifentanyl (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 remifentani 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, remifentanyl (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 remifentani 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

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 addressDeputy of Research, University of Medical Sciences,
Dr hesabi Sq.,**City**

Zahedan

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****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

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Tehran University of Medical Sciences

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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*