# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jul 2026

## 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 ≥3cm 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**

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**

Iran (Islamic Republic of)

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+98 21 7788 0909

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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 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**
*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, 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 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, 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 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 address**
Deputy 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
**Other areas of specialty/work**
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Arash women's hospital, Baghdarnia Avenue, shahid Bagheri highway, Resalat highway, Tehranpars
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## Person responsible for scientific inquiries

**Contact**
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Tehran University of Medical Sciences
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## 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*