

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of Effect Of Apotel And Remiphentanil in Pain management after elective Cesarean Section

Protocol summary

Summary

The aim of this study was to comparison of effect of Apotel And Remiphentanil in pain management after elective cesarean Section .This was double-blind study. Number Seventy patients undergoing elective cesarean section divided randomly into two groups Apotel (A) Remifentanil (R) (each group equally Weeks 35). Inclusion criteria: gestational age 37-42 weeks; 18 to 35 years; Maternal education at least fifth grade; singleton pregnancy; previous cesarean section. Exclusion criteria: unwillingness to participate; having chronic diseases; cardiac medications; respiratory problems; drug abuse; mental disorders; cancer and infectious diseases; people with chronic pain. we injected 3-5 mg per kg Propofol and 1-2 miligram per Kg Atracurium for patient .After we intubated patient. In Apotel group , we injected one gram Apotel in 200 milliliter of normal saline for 20 minutes for patient , after exit placenta and clamping umbilical cord.In the second group, we injected 0.5 micrograms per Kg per minute Remifentanil for patient, after anesthesia and exit fetus and clamping the umbilical cord to the fetus . We recorded pain in patient score with VAS 4 and 12 hours after surgery and amount of drug after 24 hours of surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100320258N12**
Registration date: **2016-10-07, 1395/07/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-07, 1395/07/16

Registrant information

Name

Fariba Farokhi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice President of Research Arak University of Medical Sciences

Expected recruitment start date

2016-09-18, 1395/06/28

Expected recruitment end date

2018-01-18, 1396/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effect Of Apotel And Remiphentanil in Pain management after elective Cesarean Section

Public title

Comparison of Effect Of Apotel And Remiphentanil in Pain management after elective Cesarean Section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 37-42 weeks; 18 to 35 years; Maternal education at least fifth grade; singleton pregnancy; previous cesarean section Exclusion criteria:

unwillingness to participate; having chronic diseases; cardiac medications; respiratory problems, drug abuse; mental disorders; cancer and infectious diseases; people with chronic pain

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University of Medical Sciences

Street address

Dr Mohammad Rafiei, Vice chancellor for research,
Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Postal code

848176941

Approval date

2016-09-18, 1395/06/28

Ethics committee reference number

IR.ARAKMU.REC.1395.202

Health conditions studied

1

Description of health condition studied

non-emergency hysterectomy

ICD-10 code

o82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Pain

Timepoint

4 and 12 hours after surgery

Method of measurement

Visual Analogue Scale

2

Description

amount of drugs

Timepoint

24 hours after operation

Method of measurement

geram

Secondary outcomes

empty

Intervention groups

1

Description

In Apotel group , we injected one gram Apotel in 200 milliliter of normal saline for 20 minutes for patient , after exit placenta and clamping umbilical cord.

Category

Treatment - Drugs

2

Description

In the second group, we injected 0.5 micrograms per Kg per minute Remifentanyl for patient, after anesthesia and exit fetus and clamping the umbilical cord to the fetus.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Katayon Vakilian

Street address

Emam Khomeini street, Taleghani hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Arak medical science university

Full name of responsible person

Dr Mohammad Rafiee

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

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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 Arak medical science university

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**

Arak medical sciences university

Full name of responsible person

Dr Katayon Vakilian

Position

PhD of pregnancy health

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Msc student of midwifery

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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