Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy of combination diclofenac suppository and tranxamic acid with diclofenac suppository and tranxamic acid alone on pain and bleeding in patients undergoing spinal anesthesia for cesarean tostoperative bleeding in patients undergoing spinal anesthesia for cesarean

Protocol summary

Summary

Objective of study: Comparison of efficacy of combination diclofenac suppository and tranxamic acid with diclofenac suppository and tranxamic acid on pain and tostoperative bleeding in patients undergoing spinal anesthesia for cesarean Inclusion criteria: pregnant women aged 18 to 40 years with spinal anesthesia for elective Caesarean section and don't have underlying disease and have satisfied for spinal anesthesia. And prohibitions for spinal anesthesia and don't have any allergy to anesthetics and other drugs. hypnotics and anti-anxiety drugs. Don't use Exclusion criteria: presence of underlying disease ban for spinal anesthesia and allergy to anesthetics and the other drugs, using hypnotics and anti-anxiety drugs in patients with hemoglobin less than 10. And patients with placenta previa and placental detachment and , placenta Acreta, placenta previa, multiple, history of thromboembolic disease and any coagulopathy patients with a BMI over 35 and kidney trouble,also people who have the problem polyhydroamnious and oligo polyhydroamnious is not in this study Population under Studying: Women 18 to 40 years old undergoing cesarean section with spinal anesthesia. Sample Size: 210 cases (three groups of 70 people) Intervention study and it's time: diclofenac suppository and tranxamic acid intravenously 5-10 min before spinal anesthesia. Primary outcomes: the amount of bleeding during cesarean

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100914961N1**

Registration date: **2013-11-21, 1392/08/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-21, 1392/08/30

Registrant information

Name

fatemeh farajisoleymani

Name of organization / entity

medical university of qazvin

Country

Iran (Islamic Republic of)

Phone

+98 28 1335 5741

Email address

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2011-04-20, 1390/01/31

Expected recruitment end date

2012-04-19, 1391/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of efficacy of combination diclofenac suppository and tranxamic acid with diclofenac suppository and tranxamic acid alone on pain and bleeding in patients undergoing spinal anesthesia for cesarean tostoperative bleeding in patients undergoing spinal anesthesia for cesarean

Public title
The effect of tranxamic acid and diclofenac suppository on reducing postoperative pain and bleeding in patients undergoing spinal anesthesia for cesarean
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: pregnant women aged 18 to 40 years ; selection for cesarean section; full satisfaction of the spinal anesthesia;have no underlying disease; don't have any prohibition for spinal anesthesia and allergy to anesthetics and the other drugs;not using Hypnotics and anti-anxiety drugs Exclusion criteria: presence of underlying disease;prohibition to spinal anesthesia and allergy to anesthetics and the other drugs; using hypnotics and anti-anxiety drugs; patients with hemoglobin less than 10;patients with detached placenta, placenta Acreta, placenta previa;multiple;history of thromboembolic disease ;any coagulopathy; patients with a BMI over 35 ; kidney trouble;polyhydroamnious and oligo hydroamnious
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **210**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The school of Medicineof Qazvin
Street address
The school of Medicineof Qazvin, Navab street, Qazvin
City
Qazvin
Postal code
3413996134
Approval date
2013-09-04, 1392/06/13
Ethics committee reference number
28/20/7899

Health conditions studied

1

Description of health condition studied
spinal anesthesia
ICD-10 code
O74
ICD-10 code description
Complications of anaesthesia during labour and delivery

Primary outcomes

1

Description
the amount of bleeding during sesarian
Timepoint
during laber and 24 hours after laber
Method of measurement
according check list (calculating gas and longas during sesarian and HB 24 hours after sesarian)

2

Description
the amount of pain after cesarian
Timepoint
during laber and 24 hours after laber
Method of measurement
according to the visual pain scale

Secondary outcomes

1

Description
the level of the pain after surgery
Timepoint
24 hours afte surgery
Method of measurement
according of VPS

Intervention groups

1

Description
The first group tranxamic acid 10 cc per kilogram of body

weight intravenously for 5 to 10 minutes before the start of the section,

Category

Treatment - Drugs

2

Description

The second group of diclofenac suppositories 100 mg, 5 to 10 minutes before the start of the section

Category

Treatment - Drugs

3

Description

The third group combination of tranxamic acid 10 cc per kilogram of body weight intravenously and diclofenac suppositories 100 mg for 5 to 10 minutes before the start of section

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Kosar Hospital

Full name of responsible person

Dr Fatemeh Farajisoleymani

Street address

Qazvin Rajayi Hospital

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The school of Medicine of Qazvin

Full name of responsible person

Dr Saeed Asefzadeh

Street address

Qazvin Rajayi Hospital

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The school of Medicine of Qazvin

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

The school of Medicine of Qazvin

Full name of responsible person

Dr Fatemeh Farajisoleymani

Position

The Assistent of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Babaei Medical University of Qazvin

Full name of responsible person

Dr Fatemeh Farajisoleymani

Position

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Person responsible for updating data

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Full name of responsible person

Dr Fatemeh Farajisoleymani

Position

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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