Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparision the analgesic effects of intravenous acetaminophen , intramuscular tramadol and suppository diclofenac in the treatment of cesarean pain

Protocol summary

Summary

In this study, intravenous pain relief and side effects of three drugs, acetaminophen, diclofenac suppository and intramuscular injection of tramadol are determined and compared. Study on 105 pregnant women over 34 weeks for elective cesarean section at Al Zahra Hospital, Tabriz Vtalqany have been done and are willing to participate in the study.The patients are taking pain medications before surgery or have a history of mental problems and anxiety are excluded. Patients were randomly divided into three equal groups of 35 persons . After entering the patient's medical department is aware of the three groups of patients, the drug. For the first group, rectal suppositories diclofenac 100 mg every 8 hours (made in Iran, drug manufacturing company) For the second group IV Acetaminophen 1g/100ml infusions every 6 hours 15 minutes (making Iran Couble drugs) And for third group , Tramadol 50mg intramuscular injection every 8 hours (made in Iran, drug manufacturing companies). Pain will be measured every 2, 6 and 24 hours after surgery whith Visual assay of pain (VAS) by scaled ruler (0 to 10). This is a double blind study. Pain is considered as the primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301235448N3**
Registration date: **2013-04-10, 1392/01/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-10, 1392/01/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

vice chancellor of research,Tabriz University of Medical Mciences

Expected recruitment start date

2013-01-29, 1391/11/10

Expected recruitment end date

2013-12-31, 1392/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision the analgesic effects of intravenous acetaminophen , intramuscular tramadol and suppository diclofenac in the treatment of cesarean pain

Public title

Comparision the analgesic effects of intravenous acetaminophen , intramuscular tramadol and suppository diclofenac in the treatment of cesarean pain

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1 - Pregnant women who are candidates for elective or emergency cesarean section to link to the list of operating room training center - Al Zahra Hospital, Tabriz and taleghany hospital have been. 2 - pregnant women over 34 weeks 3 - patient willingness to participate in the study exclusion criteria of study: 1 - Patients who have any reason to take any pain medications before surgery. 2 - Have the contra indications for NSAID or paracetamol or tramadol prescription, such as peptic ulcer, coagulopathy, renal failure, liver failure, asthma, and allergy medicines .... 3 - a history of mental problems and anxiety

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

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
Tabriz university institutional ethics review board

Street address
Third Floor, Central Building of Number2, Golgasht Street

City
Tabriz

Postal code

Approval date
2012-02-20, 1390/12/01

Ethics committee reference number
5/4/9921

Health conditions studied

1

Description of health condition studied
infertility

ICD-10 code
N97

ICD-10 code description
Female Infertility

Primary outcomes

1

Description
Pain Relief

Timepoint
Pain of 2 hours, 6 hours and 24 hours after surgery is measured

Method of measurement
Visual assay of pain (VAS) by scaled ruler (0 to 10) is zero, no pain and 10 the worst pain at the show, be assesse

Secondary outcomes

1

Description
Improve mobility

Timepoint
Up to 8 hours after surgery

Method of measurement
Questionnaire

2

Description
reduce the risk of postoperative thromboembolic disease

Timepoint
After Surgery

Method of measurement
Questionnaire

3

Description
Improve the ability of the mother to child care and breastfeeding

Timepoint
After Surgery

Method of measurement
Questionnaire

4

Description
Shorten the period of hospitalization

Timepoint
After Surgery

Method of measurement
Questionnaire

5

Description
Reduce hospital costs And increase patient satisfaction
Timepoint
After Surgery
Method of measurement
Questionnaire

Intervention groups

1

Description
Group1 versus rectal diclofenac 100 mg every 8 hours (made in Iran, drug manufacturing company)
Category
Treatment - Drugs

2

Description
In group2: IV Acetaminophen 1g/100ml infusion for 15 minutes every 6 hours in patients over 50 kg. In patients under 50 kg, 15 mg / kg every 6 hours (making Iran Couble medicine)
Category
Treatment - Drugs

3

Description
In group3: muscle tramadol 50mg injections every 8 hours (made in Iran, drug manufacturing company) will be used
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital,Taleghani Hospital
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Mciences
Full name of responsible person
vice chancellor of research
Street address
Tabriz university of medical sciences, Golgasht street, Azadi avenue
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Mciences
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
Tabriz University of Medical Sciences
Full name of responsible person
D.Fatemeh Mallah
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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