Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The effect of magnesium sulfate local injection in surgical incision for cesarean section postoperative pain control

Protocol summary

Summary

This triple blind clinical trial is conducted on 192 pregnant women who are admitted for elective cesarean section in Arak Thaleghani Hospital. After obtaining written consent, the patients are randomized and divided into two groups. Both groups undergo spinal anesthesia with 75 mg lidocaine 5%. During the operation, both groups are under standard monitoring. At the end of the surgery and before closing the wound, the intervention group is injected with a 20 ml mixture of 750 mg magnesium sulfate and normal saline locally at the site of operation and the control group receives only 20 ml of normal saline. After the surgery, all patients are followed at 4, 8, 12 and 24 hours for pain intensity by Visual Analog Scale and the amount of anti analgesic that is used during this period are calculated. For pain control in both groups, diclofenac suppositories are used and if the pain is not controlled or the VAS measurement is more than 5, meperidine 1 mg/kg intramuscular is administered. During this time all patients are observed for possible side effects such as hypo tension, dysrhythmia, diplopia, dyslexia and local pain and burning sensation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104303247N2**
Registration date: **2011-05-19, 1390/02/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-05-19, 1390/02/29

Registrant information

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Shirin Pazoki
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of magnesium sulfate local injection in surgical incision for cesarean section postoperative pain control

Public title

the effect of magnesium sulfate injection in surgical incision for postoperative pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with anesthetic class ASA1 or 2 and age range of 20 -35 years, no history of: pre eclampsia , chronic hypertension, heart, liver, kidney and mental disorders, chronic opioid abuse, calcium channel blocker medications, and elective operations.

Exclusion criteria: If the anesthetic level is not satisfactory and we have to give opioids or anesthetics during surgery or if magnesium sulfate has to be given generally for hypertensive postoperative patients

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **192**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of Medical Sciences

Street address
Postal Box 646, Alam al hoda st., Shiroodi st.

City
Arak

Postal code
3819693345

Approval date
2010-01-27, 1388/11/07

Ethics committee reference number
88-74-3

Health conditions studied

1

Description of health condition studied
Acute postoperative pain

ICD-10 code
R52.0

ICD-10 code description
Acute pain

Primary outcomes

1

Description
Postoperative pain intensity

Timepoint
4, 8, 12 and 24 hours postoperatively

Method of measurement
Visual analog Scale

2

Description
Amount of diclofenac supposetories required

Timepoint
During first 24 hour postoperatively

Method of measurement
mg

3

Description
Amount of intramuscular pethidine required

Timepoint
24 hours postoperatively

Method of measurement
Mili gram (mg)

Secondary outcomes

1

Description
Possible side effects

Timepoint
During the first 24 hour postoperatively

Method of measurement
Patients medical records

Intervention groups

1

Description
Intervention group: at the end of surgery and before closing the wound 20 ml mixture of 750 mg magnesium sulfate and normal saline is injected locally in the operation site

Category
Treatment - Drugs

2

Description
Control group: 20 ml of normal saline is injected

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Thaleghani Education and Healthcare Centre
Full name of responsible person
Shirin Pazoki
Street address
Thaleghani Education and Healthcare Centre
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Saeed Changizie Ashtiani
Street address
Pardis complex, Basij square, Enghelab square,Taleghani Ave.
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
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
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Web page address

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