Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Name

Shirin Pazoki

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1417 3502

Email address

pazooki.sh@arakmu.ac.ir

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

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Shirin Pazoki

Position
Anesthetist / Associate professor

Other areas of specialty/work

Street address
Thaleghani Education and Healthcare Centre

City
Arak

Postal code
3816149369

Phone
+98 86 1277 6063

Fax

Email
pazooki.sh@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Shirin Pazoki

Position
Anesthetist / Associate professor

Other areas of specialty/work

Street address
Taleghani education and healthcare centre

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Person responsible for updating data

Contact

Name of organization / entity
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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