Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

survey of preventive effect of intravenous magnesium sulphate on postoperative pain of pregnant women undergoing Cesarian section with general anesthesia in valiasr hospital in years: 91-92

Protocol summary

Summary
this triple blinded, randomized study involves pregnant women who are scheduled for elective Cesarian section under general anesthesia in valiasr center of Imam Khomeini university hospital. 50 pregnant women are randomly allocated into intervention and control groups.patients in intervention group are received 50 mg/kg intravenous Mg sulphate in 100 ml normal saline during 15 minutes just before anesthesia induction which is continued by 15 mg/kg/hr infusion of Mg sulphate throughout the surgery. patients in control group are only received equal volume of normal saline as placebo.at the end of surgery all patients are given diclofenac suppository(100 mg)as a postoperative analgesic and are given intravenous morphine as a rescue analgesic in ward. degree of postoperative pain is assessed at 1,6,12 and 24 hours after surgery according to short-form McGill pain questionnaire.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201212245225N3**
Registration date: **2013-01-01, 1391/10/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date
2013-01-01, 1391/10/12

Registrant information

Name
Seyed mohammad Mireskandari
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source
some part of it from educational budget of anesthesia department and the remaining from project implementers

Expected recruitment start date
2013-01-19, 1391/10/30
Expected recruitment end date
2013-03-19, 1391/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
survey of preventive effect of intravenous magnesium sulphate on postoperative pain of pregnant women undergoing Cesarian section with general anesthesia in valiasr hospital in years: 91-92

Public title
survey of preventive effect of magnesium sulphate on postoperative pain of pregnant women undergoing Cesarian section
Purpose
Prevention
Inclusion/Exclusion criteria
inclusion criteria: pregnant women with ASA I,II (American Society of Anesthesiologists) scheduled for

elective Cesarian section under general anesthesia exclusion criteria: hypermagnesemia, insufficient time for giving study drugs,sensitivity to magnesium sulphate, heart blocks,hypertension,diabetes,renal disease, cardiovascular disease,history of analgesic intake during the past 24 hours,fetal distress, multiparity

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
ethics committee of tehran university of medical sciences

Street address
ghods street,keshavarz boulvard

City
tehran

Postal code

Approval date
2012-10-19, 1391/07/28

Ethics committee reference number
90/130/1312/د

Health conditions studied

1

Description of health condition studied
pregnancy

ICD-10 code
O75.8

ICD-10 code description
Other specified complications of labour and delivery

Primary outcomes

1

Description
severity of postoperative pain

Timepoint
1st, 6th,12th,24th hours after cesarian section

Method of measurement
short MCGillL pain questionaire

Secondary outcomes

1

Description
hemodynamic changes(blood pressure and heart rate)

Timepoint
at induction and tracheal intubation and during surgical procedure and in recovery period

Method of measurement
by means of a mercury manometre and a cardiac monitor

2

Description
analgesic requirements

Timepoint
during 24 hours after completion of cesarian section

Method of measurement
by means of recorded amounts of infused analgesic which displayed on a PCA pomp

Intervention groups

1

Description
.patients in control group only received equal amount of normal saline as placebo.

Category
Placebo

2

Description
patients in intervention group were received 50 mg/kg intravenous Mg sulphate in 100 ml normal saline in 15 minutes just before surgical incision and 15 mg/kg/hr IV infusion of Mg sulphate thereafter.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital (Imam Khomeini hospital)

Full name of responsible person

Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Dr amir arvin sazegar
Street address
office of hospital, valiasr hospital , imam khomeini complex, Keshavarz boulvard
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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Person responsible for updating data

Contact

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