Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparative evaluation of effect of IV Dexamethasone on post-cesarean pain

Protocol summary

Summary

Comparative evaluation of effect of IV Dexamethasone on post-cesarean pain Introduction: operations lead to body stress and tissue injury that cause pain and many complications due to pain. Purpose of this study is to evaluate the effect of IV administration of Dexamethasone on pain reduction after caesarean. Methods and Materials :In a randomized double-blinded clinical trial we select 60 G1 women who are candidated for single elective caesarean at beheshti hospital and did not have any sensitivity or allergy to glucocorticoids; present or past history of PUD(peptic ulcer disease), glaucoma, DM(Diabete Mellitus) 1,2, heart failure, fungal or viral systemic infection, HTN (Hypertention) or any other poor-controlled disease and divide them randomly into 2 groups (8 mg dexamethasone or2 cc normal salin recipient)and then we recorde variables such as MAP (Mean Arterial blood Pressure, HR (heart rate), RR (respiratory rate), pain and vomiting severity based on VAS (Visual Analogue Scale) and morphine and methoclopramide consumption and finally analyzed data by t test and ManWitney test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104095934N2**
Registration date: **2012-07-21, 1391/04/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-07-21, 1391/04/31

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2012-08-05, 1391/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of effect of IV Dexamethasone on post-cesarean pain

Public title

Effect of dexamethasone on reduction of pain after cesarean section.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: healthy pregnant, single baby and full term (G1) women who were candidated for elective cesarean in Beheshti hospital. Exclusion criteria: any sensitivity or allergy to glucocorticoids; present or past history of PUD(peptic ulcer disease), glaucoma, DM(

Diabete Mellitus) 1,2, heart failure, fungal or viral systemic infection, HTN (Hypertention) or any other poor-controlled disease.

Age
From **18 years** old to **34 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Scienses

Street address
Hezarjarib avenue-Isfahan

City
Isfahan

Postal code
8174673461

Approval date
2009-05-24, 1388/03/03

Ethics committee reference number
388122

Health conditions studied

1

Description of health condition studied
Pain after celective cesarean

ICD-10 code
(O80-O84De

ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
Effect of IV Dexamethasone on post-cesarean pain

Timepoint
At at time of 0, 15, 30, 60 min and 2, 4, 6, 12, 18, 24 hours after CS

Method of measurement
Severity of pain and vomiting (base on VAS) was measured by giving a 10cm ruler to the patients .VAS (Visual Analogue Scale) is a method of pain evaluation by using a 10cm.in this method, the patient will be asked to indicate zero in case of having no pain and ten in case of having the most sever pain

2

Description
Effect of IV dexamethasone on reduction of morphine consumption after cesarean section

Timepoint
All the patients receive one routine dose of morphine at recovery room and then if need with intervals of 4 hours. Morphin consomption rate is recorded and in the end will be evaluated.

Method of measurement
Results which are recorded based on miligrams

3

Description
Effect of IV Dexamethasone on reduction of vomiting and methoclopramide consumption after cesarean section

Timepoint
Monitored at time of 0, 15, 30, 60 min and 2, 4, 6, 12, 18, 24 hours after CS

Method of measurement
Severity of pain and vomiting (base on VAS) is measured by giving a 10cm ruler to the patients .VAS (Visual Analogue Scale) is a method of pain and vomiting evaluation by using a 10cm.in this method, the patient will be asked to indicate zero in case of having no vomiting and ten in case of having the most sever vomiting. we considered VAS score 1-3 as mild,4-7 as moderate and 7-10 as sever.Rescue antiemetic (methoclopramide 10 mg,) was given if vomiting occurrs or at parturientś request. treatment is repeated if necessary.and total dose of methoclopramide will be recorded

Secondary outcomes

1

Description
Effect of IV dexamethasone on vital sign (MAP (mean arterial pressure),HR (heart rate),RR(respiratory rate)

Timepoint
At times of 0, 15, 30, 60 min and 2, 4, 6, 12, 18, 24 hours after CS

Method of measurement
By using a sphigmomanometer for blood pressure and a digital watch for RR and HR

Intervention groups

1

Description
we administer 8 mg of IV dexamethasone to case group
Category
Treatment - Drugs

2

Description
the control group receive 2 cc normal saline at the same time
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital -the operation room
Full name of responsible person
dr Azar Danesh Shahraki-assistant professor
Street address
Isfahan-Beheshti Hospital-gynecology and obstetrics department
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences, research unit
Full name of responsible person
Mr Moradi
Street address
research unit, faculty of medicine, Isfahan university of medical scienses, hezarjarib avenue, isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences, research unit
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
Medicine college, Isfahan University of Medical Sciences
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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