

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 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 candidates 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 or 2 cc normal saline recipient)and then we record 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

Name

Mahdi Babaei

Name of organization / entity

Isfahan University of Medical Sciences-Dentistry college

Country

Iran (Islamic Republic of)

Phone

+98 31 1788 3314

Email address

babaei@edc.mui.ac.ir

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 candidates 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 Sciences

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 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 occurs or at parturient's 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 sciences, 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

Full name of responsible person

Shadi Nouri

Position

MD student

Other areas of specialty/work

Street address

Golestan lalley-Shafagh Bulvard-Keshavarz Bulvard-Isfahan

City

Isfahan

Postal code

Phone

+98 31 1788 3314

Fax

Email

babaei@edc.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Azar Danesh Shahraki

Position

MD, Gynecologist(obstetrivian)

Other areas of specialty/work

Street address

Golestan Alley-near Dey labratory-Middle Tohid Avenue

City

Isfahan

Postal code

Phone

+98 31 1628 6949

Fax

Email

danesh@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Medicine college, Isfahan University of Medical Sciences

Full name of responsible person

Shadi Nouri

Position

MD student

Other areas of specialty/work

Street address

Golestan lalley- Shafagh Bulvard-Keshavarz Bulvard-

City

Isfahan

Postal code**Phone**

+98 31 1788 3314

Fax**Email**

babaei@edc.mui.ac.ir

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