Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparitive prophylactic effect of pregabalin versus aminophylline plus dexamethasone in preventing postdural puncture headache in caesarian delivery.A double blind clinical trial.

Protocol summary

Summary

Summary : The aim of this study is to compare prophylactic effect of pregabalin versus aminophylline plus dexamethasone in preventing postdural puncture headache in caesarian delivery. Inclusion criteria are elective cesarian and age between 18 -45. Exclusion criteria are history of sensitivity to medication; chronic headace and any condition that contraindicate spinal anesthesia.In a double blind randomized clinical trail 300 patients will be divided to three equals group(n=100) All the patients in control group receive placebo(oral capsule like pregabelin and intravenous salin as aminophylline plus dexamethasone) . In two case groups all the patients receive prophylactic pregabalin(60 mg) after dilivery of fetus or aminophylline plus dexamethasone .Headace , need to analgesic drugs, patient satisfaction and time of discharge will be recorded and analyzed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601161936N16**
Registration date: **2016-02-22, 1394/12/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-22, 1394/12/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2015-04-01, 1394/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparitive prophylactic effect of pregabalin versus aminophylline plus dexamethasone in preventing postdural puncture headache in caesarian delivery.A double blind clinical trial.

Public title

Comparitive prophylactic effect of pregabalin versus aminophylline plus dexamethasone in preventing postdural puncture headache in caesarian delivery.A double blind clinical trial.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all patients who are candidates for elective cesarian and age between 18 -45. Exclusion criteria: history of sensitivity to medication; chronic

headace and any condition that contraindicate spinal anesthesia.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

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

Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences -Siraf Street

City

Bushehr

Postal code

Approval date

2015-07-20, 1394/04/29

Ethics committee reference number

BPUMS/REC.11394.13

Health conditions studied

1

Description of health condition studied

prophylactic effect of pregabalin versus aminophylline plus dexamethasone in preventing postdural puncture headache

ICD-10 code

M79.9

ICD-10 code description

Soft tissue disorder, unspecified

Primary outcomes

1

Description

Post spinal headace

Timepoint

Two weeks

Method of measurement

Question

Secondary outcomes

1

Description

Patient satisfication

Timepoint

Two weeks

Method of measurement

Question

Intervention groups

1

Description

Group C received saline (placebo) i.v in similar volume of dexamethasone plus aminophylline and the oral placebo capsule 3 times a day

Category

Treatment - Drugs

2

Description

Group P(pregabaline) receive 100mg oral pregabaline capsule 3 times a day (each 8 hour) before onset of headache and saline i.v. in similar volume of dexamethasone plus aminophylline as placebo for blinding the study

Category

Treatment - Drugs

3

Description

Group A(aminophylline plus dexamethasone) receive aminophylline 1.5 mg/kg i.v. plus dexamethasone 0.1 mg/kg i.v and a placebo oral capsule similar in shape to the pregabaline 3 times a day thirty minutes after umbilical cord clamping.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye khalig fars Hospital

Full name of responsible person

Dr. Abdolreza Najafi Anaraki

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Bushehr University of Medical Sciences ,Siraf
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Bushehr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Dr Majid Asadi
Street address
Bushehr University of Medical Sciences، Siraf
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bushehr 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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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