

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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

##### Name

Abdolreza Najafi Anaraki

##### Name of organization / entity

Bushehr University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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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

headache 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 headache

**Timepoint**

Two weeks

**Method of measurement**

Question

**Secondary outcomes****1****Description**

Patient satisfaction

**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(pregabalin ) receive 100mg oral pregabalin 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 pregabalin 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

**Street address**

Bushehr University of Medical Sciences ,Siraf

**City**

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****Contact****Name of organization / entity**

Bushehr University of Medical Sciences

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**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*