# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The study of adjunctive Progesterone therapy effectiveness in intractable catamenial epilepsy

## Protocol summary

**Summary**

Because of the different ideas about epilepsy progesterone therapy this prospective double blind randomized clinical trial study conducted to investigate the efficacy of Progesterone as adjunctive therapy in intractable catamenial epilepsy. Subjects were 38 women between 18-40 years of age with intractable catamenial epilepsy who had clinically and electrographically documented refractory CPS, SGS, PGS. They were taking full dose antiepileptic drugs. They were divided into 2 groups by Random Allocation software. First group was taking antiepileptic drugs (AEDs) plus placebo and the second used progesterone (240 mg progesterone tablet (Majestrol) twice a day) additionally. Quality Indexes were done by Independent Sample t-Test and Fisher exact Test or Chi-Square applied for relative frequency comparison in two groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201202128660N1**
Registration date: **2012-02-22, 1390/12/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2012-02-22, 1390/12/03

**Registrant information**

**Name**

Maedeh Mirmohamadsadeghi

**Name of organization / entity**

Isfahan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 1625 5555

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Isfahan University of Medical Sciences

**Expected recruitment start date**

2010-06-01, 1389/03/11

**Expected recruitment end date**

2010-12-01, 1389/09/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The study of adjunctive Progesterone therapy effectiveness in intractable catamenial epilepsy

**Public title**

Progesterone therapy effectiveness in treatment of intractable catamenial epilepsy

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1- The women between 18 and 45 years of age who had clinically and electrographically documented refractory CPS or SGMS of temporal lobe origin; 2- All the women with demonstrated catamenial pattern of seizure exacerbation premenstrually between days 25 and 2 or during the entire luteal phase of the menstrual cycle between days 2 and 10; 3- The women with seizure exacerbation during the entire luteal phase with inadequate luteal phase cycles as documented by low serum progesterone levels less than 5 ng/ml during

the mid-luteal phase; 5- The women who had premenstrual exacerbations with normal mid-luteal phase progesterone levels; 6- No pregnant and not lactating women who had no amenorrhea or had taken no major tranquilizers, antidepressant medications or OCP during 3 month prior to participate. Exclusion criteria: 1- Immigration; 2- Inaccessibility; 3- Giving up the participation; 4- Sever progesterone complications.

**Age**
From **18 years** old to **40 years** old

**Gender**
Female

**Phase**
2

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **38**

**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**
Vice chancellor for research, Isfahan University of Medical Sciences

**Street address**
Hezar Jarib

**City**
Isfahan

**Postal code**

**Approval date**
2010-08-20, 1389/05/29

**Ethics committee reference number**
389291

## Health conditions studied

### 1

**Description of health condition studied**
Epilepsy

**ICD-10 code**
G40.2

**ICD-10 code description**
Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures

## Primary outcomes

### 1

**Description**
Seizure frequency

**Timepoint**
3 months

**Method of measurement**
questionnaire

## Secondary outcomes

### 1

**Description**
Seizure frequencies per month

**Timepoint**
1 month

**Method of measurement**
questionnaire

## Intervention groups

### 1

**Description**
antiepileptic drugs + placebo

**Category**
Placebo

### 2

**Description**
antiepileptic drugs, intervention with 240 mg of progestron (Mejestrol) tablets twice a day

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
private office

**Full name of responsible person**

**Street address**

**City**
Isfahan

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Research Department, Medical school, Isfahan

University of Medical Sciences

**Full name of responsible person**

Dr. Taleb Azarm

**Street address**

Medical school, Isfahan University of Medical Sciences, Hezar jarib

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Department, Medical school, Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Mohammadreza Najafi

**Position**

Associated professor of Neurology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Maedeh Mirmahamadsadeghi

**Position**

resident of Neurology

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## Person responsible for updating data

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Isfahan University of Medical Sciences

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Maedeh Mirmohamadsadeghi

**Position**

Resident Neurology

**Other areas of specialty/work**

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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*