

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Evaluating the effects of treatment with amitriptyline as a tricyclic antidepressant drug on serum prolactin levels in patients with chronic migraine and its relation with patient's quality of life and function

#### Protocol summary

##### Study aim

Evaluating the effects of treatment with amitriptyline as a tricyclic antidepressant drug on serum prolactin levels in patients with chronic migraine and its relation with patient's quality of life and function

##### Design

Cases in pilot study consist of 20 patients and they will be evaluated in a before- after manner

##### Settings and conduct

Study will be conducted on Kosar Hospital of Semnan patients. General information about patients and also their quality of life as well as their serum prolactin levels will be gathered

##### Participants/Inclusion and exclusion criteria

Inclusion: patients with chronic migraine with or without typical aura  
Exclusion: hyperprolactinoma, hypothalamus-hypophysis diseases, recent head or chest trauma, kidney or hepatic failure, PCOD, menstrual irregularity or menopause, depression or anxiety, anorexia, thyroid problems, convulsive disorders, pregnancy, taking antidepressants or anti-psychotics, heart conditions, glaucoma or any contraindication to TCAs in patients

##### Intervention groups

In this study we evaluate serum prolactin levels as well as life quality in patients with migraine who need preservative treatment before starting and 2 months after treatment with amitriptyline and we analyze the changes and their relation to each other

##### Main outcome variables

Evaluation of the effects of serum prolactin changes in response to treatment with amitriptyline on patients' quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211013052758N1**  
Registration date: **2021-11-03, 1400/08/12**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-03, 1400/08/12**

Update count: **0**

##### Registration date

2021-11-03, 1400/08/12

##### Registrant information

##### Name

negar emadeddin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8867 1907

##### Email address

negaremedi.92@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-02, 1400/08/11

##### Expected recruitment end date

2022-11-02, 1401/08/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effects of treatment with amitriptyline as a

tricyclic antidepressant drug on serum prolactin levels in patients with chronic migraine and its relation with patient's quality of life and function

#### Public title

Evaluating the effects of treatment with amitriptyline as a tricyclic antidepressant drug on serum prolactin levels in patients with chronic migraine and its relation with patient's quality of life and function

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

patients with migraine without aura who need preservative treatment patients with migraine with classic aura who need preservative treatment

##### Exclusion criteria:

anything that might affect serum prolactin levels in patients including medications or comorbidities contraindications of TCAs prescription such as heart disease or anaphylaxis

#### Age

No age limit

#### Gender

Both

#### Phase

1-2

#### Groups that have been masked

No information

#### Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

evaluation of serum prolactin levels and also patients quality of life based on a standard questionnaire

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Other

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

###### Street address

5th floor , No.5 - 19th st. , Gandhi st. , Tehran , Tehran

#### City

Semnan

#### Province

Semnan

#### Postal code

1517865433

#### Approval date

2021-10-31, 1400/08/09

#### Ethics committee reference number

IR.SEMUMS.REC.1400.186

### Health conditions studied

#### 1

##### Description of health condition studied

migraine

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

effects of amitriptyline induced serum prolactin level changes on migraine patients quality of life

##### Timepoint

before starting treatment and 2 month after starting treatment with amitriptyline

##### Method of measurement

prolactin serum level test (ELISA) - Headache impact test (HIT) questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: patients with migraine with typical aura or without aura

##### Category

Treatment - Other

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Kosar hospital of Semnan

###### Full name of responsible person

Negar Emadeddin

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5th floor, No. 5 , 19th st. , Gandhi st. , Tehran , Tehran

###### City

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**Province**  
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negaremedi.92@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
Negar Emadeddin  
**Street address**  
5th floor, No. 5 , 19th st. , Gandhi st. , Tehran ,  
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semnan  
**Province**  
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negaremedi.92@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Semnan University of Medical Sciences  
**Proportion provided by this source**  
60  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
Negar Emadeddin  
**Position**  
medical student  
**Latest degree**  
A Level or less

#### Other areas of specialty/work

Others  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

data include patients general data as demographic data also information about patients history and treatments they take as well as the results of patients serum prolactin test and quality of life.

**When the data will become available and for how long**

accessibility 12 month after publish of the results

**To whom data/document is available**

researchers and industries

**Under which criteria data/document could be used**

any usage of data and/or information relating to this study should first be confirmed by people conducting this study

**From where data/document is obtainable**

any request can be sent via mail to negaremedi.92@gmail.com or asked by visiting Semnan university of medical science

**What processes are involved for a request to access data/document**

sending request filling permission forms waiting to respond

**Comments**