

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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 updating data

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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