

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Metformin in the control of weight gain related to sodium valproate administration in adults

Protocol summary

Summary

This study aimed to assess the effectiveness of metformin in the control of weight gain related to sodium valproate medication. Study population is 50 adult patients with migraine receiving sodium valproate referred to Yahyanejad Clinic who have inclusion criteria and do not have exclusion criteria. These patients will be allocated randomly in four groups. The first intervention group, included 10 persons, 500 milligram metformin (ARYA Company) in a day for twelve weeks, the second intervention group, included 10 persons, 500-1000 milligram metformin in a day for twelve weeks, and the third intervention group, included 10 persons, 1000-2000 milligram metformin in a day for twelve weeks will be prescribed. The control group, included 20 patients, will receive only education for improvement of nutrition regimen in addition to placebo. Also, nutrition improvement will be educated face-to-face in the three intervention groups. At baseline, all of the four groups will be interviewed by a psychiatrist, also, quality of life, weight, body mass index, waist circumference, blood pressure, blood sugar and lipids, renal and hepatic function will be examined. After 4, 8 and 12 weeks of metformin administration, side-effects, drug tolerance, besides weight and body mass index will be assessed. At the end of the 12th week, anthropometric measurements, blood pressure, venous blood tests and quality of life of the patients will be evaluated again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071322991N8**

Registration date: **2017-08-16, 1396/05/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-16, 1396/05/25

Registrant information

Name

Sussan Moudi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 5683

Email address

sussan.mouodi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Metformin in the control of weight gain related to sodium valproate administration in adults

Public title

Metformin for control of weight gain related to sodium valproate administration in adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 65 years; under medication with sodium valproate for at least one month; self-reported weight gain more than three kilogram after sodium valproate administration; filling and assignment the informed consent form
Exclusion criteria: diabetes in the patient; endocrine disorder in which the patient is treated with steroids; administration other psychotropic drugs except sodium valproate; suspect to polycystic ovarian disease in the patient; mental retardation or other severe physical or mental disorders which inhibit the cooperation of the patient in the research; pregnancy and breast-feeding; impairment of renal or hepatic function (creatinine or liver enzymes more than 150 percent higher than normal value); alcohol, narcotic and psychotropic drugs consumption

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz avenue

City

Babol

Postal code

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

MUBABOL.REC.1396.15

Health conditions studied

1

Description of health condition studied

Association of metformin and control of weight gain related to sodium valproate administration in adults

ICD-10 code

F99

ICD-10 code description

Unspecified mental disorder

Primary outcomes

1

Description

Weight of the patient

Timepoint

4th, 8th and 12th weeks after intervention

Method of measurement

Digital scale

2

Description

Body Mass Index

Timepoint

4th, 8th and 12th weeks after intervention

Method of measurement

Weight (kilogram) divided by squared height (meter)

Secondary outcomes

1

Description

Drug side-effects

Timepoint

4th, 8th and 12th weeks after intervention

Method of measurement

Patient visit

2

Description

Quality of life

Timepoint

12 weeks after intervention

Method of measurement

SF-36 quality of life questionnaire

Intervention groups

1

Description

Intervention group 1: 500 milligram metformin (manufactured in ARYA Company) in a day in addition to nutrition education for twelve weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: 500-1000 milligram metformin (manufactured in ARYA Company) in a day in addition to nutrition education for twelve weeks

Category

Treatment - Drugs

3

Description

Intervention group 3: 1000-2000 milligram metformin (manufactured in ARYA Company) in a day in addition to nutrition education for twelve weeks

Category

Treatment - Drugs

4

Description

Control group: placebo in addition to nutrition education for twelve weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanejad Hospital

Full name of responsible person

Sussan Moudi

Street address

Yahyanejad Hospital, Babol

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Babol University of Medical Sciences

Full name of responsible person

Ali Akbar Moghadamnia, PhD

Street address

Babol University of Medical Sciences, Ganjafrooz avenue, Babol

City

Babol

Grant name

Grant code / Reference number

3513

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

Yes

Title of funding source

Vice chancellor for research of Babol 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

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi

Position

Assistant Professor of Psychiatry

Other areas of specialty/work

Street address

Department of Psychiatry, Yahyanejad Hospital, Babol

City

Babol

Postal code

Phone

+98 11 3219 0624

Fax

Email

sussan.mouodi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi

Position

Assistant Professor of Psychiatry

Other areas of specialty/work

Street address

Department of Psychiatry, Yahyanejad Hospital, Babol

City

Babol

Postal code

Phone

+98 11 3219 0624

Fax

Email

sussan.mouodi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi

Position

Assistant Professor of Psychiatry

Other areas of specialty/work

Street address

Department of Psychiatry, Yahyanejad Hospital, Babol

City

Babol

Postal code

Phone

+98 11 3219 0624

Fax

Email

sussan.mouodi@gmail.com

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