

# 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

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#### 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

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#### Full name of responsible person

Sussan Moudi

#### Position

Assistant Professor of Psychiatry

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Babol University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor of Psychiatry

**Other areas of specialty/work**

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**Email**

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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*