Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Clinical Trial Of Investigation of Efficacy of Metformin on the Body Mass Index of Patients under Treatment with Selective Serotonin Re uptake Inhibitors Drugs Referred to Psychiatry Clinics of Rasht

Protocol summary

Study aim

This study was designed to evaluate the effect of metformin on body mass index of patients undergoing SSRI in a randomized clinical trial.

Design

Patients will be included in the study after obtaining informed consent with admission and admission criteria. Then, 60 overweight subjects will be allocated randomly to the study groups (the metformin receiving group, the control group, and the lack of metformin). If the patients in the control group suffer from metabolic disorders requiring treatment, Are excluded. This study is in phase 3 and patients and therapists are aware of the study.

Settings and conduct

The location of the study is Shafa Psychiatric Hospital of Rasht. After sampling by available method, the specimens were randomly divided into two groups of case and control. The intervention will be given to certain people who have changed weight and body mass index for taking serotonin re uptake inhibitors, and a certain dose of metformin is given.

Participants/Inclusion and exclusion criteria

patients with anxiety and depression who referred to the Psychiatric Center. Inclusion criteria: 1- Obtain informed.2-No history of side effects with metformin and Selective serotonin re uptake inhibitor drugs.3- The absence of kidney and liver disorders. 4-The absence of a physical illness. 5- No taking Corticosteroids. 6-The absence of psychotic features. Exclusion criteria: Having Metabolic disorders (Without taking metformin), addiction

Intervention groups

Intervention group: The metformin is given to the intervention group. The usual treatment (fluoxetine , sertraline , paroxetine with a maximum daily dose) will also be received. Control group: Control subjects receive only routine treatment (fluoxetine treatment, sertraline, paroxetine with a maximum daily dose).

Main outcome variables

Changes in body mass index and Anthropometric indices due to metformin use.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140102016035N3**
Registration date: **2019-07-03, 1398/04/12**
Registration timing: **prospective**

Last update: **2019-07-03, 1398/04/12**
Update count: **0**

Registration date

2019-07-03, 1398/04/12

Registrant information

Name

somayeh shokrgozar

Name of organization / entity

guilan university of madical sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-06, 1398/04/15

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical Trial Of Investigation of Efficacy of Metformin on the Body Mass Index of Patients under Treatment with Selective Serotonin Re uptake Inhibitors Drugs Referred to Psychiatry Clinics of Rasht

Public title
Metformin and Body Mass Index of Patients under Treatment with SSRI
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Obtain informed consent from patients No history of side effects with metformin and SSRI drugs The absence of kidney and liver disorders The absence of a physical illness such as diabetes and Autoimmune disease No taking Corticosteroids Not taking any type of drug and stimulant The absence of psychotic features
Exclusion criteria:
Addiction Having metabolic disorders
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After determining overweight patients, a psychiatric assistant will randomly divide them into two groups of intervention and control. Patients with the ability to enter this clinical trial are categorized as 1 to 1 in two groups of intervention and control. Given that the total number of samples is 60, the randomization process is performed using 15 blocks of four. Both groups of patients will be described in terms of how to study and receive or not receive metformin.
Blinding (investigator's opinion)
Not 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 Guilan University of Medical Sciences
Street address
Deputy of Research and Technology University, The old building of the School of Health, in front of 17shahrivar Hospital, Shahid Siadati St., Namjoo St
City
Rasht
Province
Guilan
Postal code
41446-66949
Approval date
2019-06-12, 1398/03/22
Ethics committee reference number
IR.GUMS.REC.1398.097

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66.1
ICD-10 code description
Drug-induced obesity

2

Description of health condition studied
Depression
ICD-10 code
F32.2
ICD-10 code description
Major depressive disorder, single episode, severe without psychotic features

3

Description of health condition studied
Anxiety Disorders
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

Primary outcomes

1

Description
Fasting Blood Glucose
Timepoint
At the start of treatment, in the third and sixth months of follow up, fasting blood glucose (Kate: Pars Test) will be

measured by a psychiatrist's assistant and will be recorded in the patient records.

Method of measurement

Fasting blood glucose (kits: pars test), are measured by a psychiatrist's assistant.

2

Description

Cholesterol

Timepoint

At the start of treatment, in the third and sixth months of follow up, Cholesterol (Kate: Pars Test) will be measured by a psychiatrist's assistant and will be recorded in the patient records.

Method of measurement

Cholesterol(kits: pars test), are measured by a psychiatrist's assistant.

3

Description

Triglyceride

Timepoint

At the start of treatment, in the third and sixth months of follow up, Triglyceride (Kate: Pars Test) will be measured by a psychiatrist's assistant and will be recorded in the patient records.

Method of measurement

Triglyceride (kits: pars test), are measured by a psychiatrist's assistant.

4

Description

Height

Timepoint

At the onset of treatment, in the third and sixth months of follow up, the height (By centimeters) will be measured by the assistant psychiatrist.

Method of measurement

The height (By centimeters) will be measured by the assistant psychiatrist.

5

Description

Weight

Timepoint

At the start of treatment, in the third and sixth months of follow-up, the weight (measured by the digital scale of the Race of Germany, with a precision of one tenth kilogram) will be measured by the assistant psychiatrist.

Method of measurement

The weight (measured by the digital scale of the Race of Germany, with a precision of one tenth kilogram) will be measured by a psychiatrist's assistant.

6

Description

Body Mass Index

Timepoint

At the start of treatment, in the third and sixth follow up, the BMI will be measured by the psychiatrist's assistant (by the formula for dividing the body weight per kg by the second strength per meter).

Method of measurement

The BMI will be measured by the psychiatrist's assistant (by the formula for dividing the body weight per kg by the second strength per meter).

7

Description

Waist

Timepoint

At the start of treatment, in the third and sixth follow up, the waist (measured by centimeters) will be measured by the psychiatrist's assistant.

Method of measurement

The waist (measured by centimeters) will be measured by the psychiatrist's assistant.

8

Description

Wrist

Timepoint

At the start of treatment, in the third and sixth follow up, the wrist (measured by centimeters) will be measured by the psychiatrist's assistant.

Method of measurement

The wrist (measured by centimeters) will be measured by the psychiatrist's assistant.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Metformin that produced by the Rohamet Pharmaceutical Company, is given to the intervention group. At baseline, third and sixth month of follow-up, Weight, body mass index, waist size, wrist circumference, FBS of patients will be measured by a psychiatrist's assistant. The dose of metformin, according to previous studies, is 250 mg daily, which is based on studies of the maximum daily dose of metformin. Before lunch, metformin is given and after 4 days, it increases to 250 mg twice daily before lunch and dinner and Finally, a maximum of 2,250 mg per day is increased in three divided doses before breakfast, lunch and dinner. Patients will receive routine drug treatment (SSRI treatment).

Category

Treatment - Drugs

2

Description

Control group: The intervention in the control group will

be routinely treated (Treatment with selective serotonin re uptake inhibitors) and no additional work will be done.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
University Clinics of Psychiatry (Shafa psychiatric Hospital) And private psychiatric clinic in Rash

Full name of responsible person
Somayeh Shokrgozar

Street address
Shafa Hospital, 15khordad St., Rasht

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Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Shadman Nemati

Street address
Deputy of Research and Technology University, The old building of the School of Health, in front of 17 shahrivar Hospital, Shahid Siadati St., Namjoo St.

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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
Rasht University of Medical Sciences

Proportion provided by this source
100

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
Rasht University of Medical Sciences

Full name of responsible person
Somayeh Shokrgozar

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

Contact

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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

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Full name of responsible person
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Research expert

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Master

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Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only part of the data, such as the key outcome information or the like, can share.

When the data will become available and for how long
The beginning of the access period since early 1399

To whom data/document is available
It will be available to doctors and researchers working in academic and academic institutions.

Under which criteria data/document could be used
Eligible persons can send their application by e-mail to access relevant information so that they can be sent to them if they identify the project implementer.

From where data/document is obtainable
Email to head of project

What processes are involved for a request to access data/document
After the email is submitted to the head of project, the requesting person will receive the response within a few days.

Comments