Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The use of viola odorata syrup on depression in hospitals and clinics affiliated to the Islamic Azad University of Tehran

Protocol summary

Study aim
Investigating the effect of Viola Odorata using a questionnaire (Beck) to investigate the improvement of mild to moderate depression

Design
Clinical trial with control and intervention group, based on community and practical, parallel and single-blinded and randomized on 60 patients.

Settings and conduct
In this clinical trial study, the effect of Viola Odorata syrup on mild depression of 60 patients will be examined. We select patients over 15 years of age who referred to the hospitals and clinics of Tehran Azad University and were diagnosed with mild to moderate depression. We will divide the patients into two groups, those receiving syrup containing Viola Odorata and those receiving placebo. All patients will receive a standard regimen containing SSRI antidepressants. In addition to the standard treatment, the experimental group will receive syrup containing Viola Odorata daily. The control group will receive a placebo instead of syrup containing Viola Odorata.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with mild to moderate depression over 15 years old. exclusion criteria: Pregnant and Breast-feeding women and patients with liver and kidney failure.

Intervention groups
60 patients over 15 years old with mild to moderate depression, confirmed by a psychiatrist, will be selected. Half of these individuals, placed in the intervention group using a random number table, will receive SSRI medication and Viola Odorata syrup for a period of 3 months. The outcome variable will be assessed every two weeks after starting treatment. The other half of the study participants will be placed in the control group and will receive the SSRI medication, with the difference being that instead of Viola Odorata syrup, they will receive a placebo.

Main outcome variables
Improvement score in the Beck questionnaires

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150706023084N19**
Registration date: **2024-05-09, 1403/02/20**
Registration timing: **prospective**

Last update: **2024-05-09, 1403/02/20**
Update count: **0**

Registration date
2024-05-09, 1403/02/20

Registrant information

Name
MARYAM SHIEHMORTEZA

Name of organization / entity
AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01

Expected recruitment end date
2024-08-22, 1403/06/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The use of viola odorata syrup on depression in hospitals and clinics affiliated to the Islamic Azad University of Tehran

Public title

The use of viola odorata syrup on depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Minor to moderate depression disorder Use of SSRIs by control group Age range over 15 years

Exclusion criteria:

Pregnant women Breast feeding women GFR under 30 & child pugh B - C (Renal & Liver failure)

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the study, each patient is assigned a code(1 or 2) using Rand number. Conventionally, the patient who received code one will receive drug and the patient who received code two will receive placebo. It should be noted that the patients will not know what code they have received and only the researcher will be aware of this issue.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be single blinded in such a way that the participants will not be aware of the contents of the medicine package they receive. A code will be assigned to each patient using Rand number. Patients with a code of 1 will receive the drug, while patients with a code of 2 will receive a placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق واحد علوم دارویی دانشگاه علوم پزشکی آزاد اسلامی تهران

Street address

Dr Shariati Ave., Gholhak, Yakhchal Ave., Islamic Azad University of Pharmaceutical Sciences Branch

City

Tehran

Province

Tehran

Postal code

193956466

Approval date

2023-12-27, 1402/10/06

Ethics committee reference number

IR.IAU.PS.REC.1402.554

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description

Depression recovery degree according to Beck questionnaire

Timepoint

14 day

Method of measurement

Beck depression questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients over 15 years old with mild to moderate depression, confirmed by a psychiatrist, will be selected to use a Viola Odorata syrup made by Barij Essence Pharmaceutical Company once a day for a period of 3 months, in addition to taking an SSRI medication. Their improvement will be evaluated every two weeks through a Beck questionnaire.

Category

Treatment - Drugs

2

Description
Control group: 30 patients in the control group will receive the SSRI drug, similar to the intervention group. However, instead of receiving Viola Odorata syrup, they will receive a placebo syrup made by Barij Essence Pharmaceutical Company once a day for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu Ali hospital
Full name of responsible person
Zeinab Nazari
Street address
Damavand street, not reaching Imam Hossein square, Bu Ali hospital
City
Tehran
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Postal code
1711734365
Phone
+98 21 3334 8036
Email
booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Barij Essence Pharmaceutical company
Full name of responsible person
Laleh Hejazi
Street address
NO.78, Aryafar Ave., Marzdaran Blvd., Tehran Province
City
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Province
Tehran
Postal code
۱۴۶۴۶۵۳۴۷۱
Phone
+98 21 4426 7992
Email
crm@barijessence.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Barij Essence Pharmaceutical company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Shiehmorteza
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zeinab Nazari

Position

Pharmacy student

Latest degree

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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

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

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

Data are collected in the form of a questionnaire

When the data will become available and for how long

After the intervention

To whom data/document is available

Qualified persons

Under which criteria data/document could be used

Use for scientific advancement in the field under study

From where data/document is obtainable

Clinical office of Islamic Azad University Medical science of Tehran -Faculty of Pharmacy

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

Request in writing by going through legal procedures

Comments