Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of tricyclic antidepressant augmentation with herbal formation Hypericum perforatum and placebo in depressed outpatients referred to psychiatric clinic and Golestan hospital / Ahvaz /Iran

Protocol summary

Summary

The aim of this double blind study the therapeutic effects of medicinal products with Hypericum is an antidepressant. 40 depressed patients referred to psychiatric clinic with a diagnosis of depression based on TR DSM-IV criteria for diagnosis are studied. Patients randomly divided into two groups and a group of tricyclic antidepressants in treating depression and a range of moderate Hypericum tablets three times daily for 6 weeks and another group tricyclic antidepressants in the range of moderate depression and a number placebo tablets three times daily for 6 weeks received. Before intervention and at three and six weeks with a severely depressed therapist measured by Beck Depression Inventory and the two groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010124917N1**
Registration date: **2011-01-20, 1389/10/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-01-20, 1389/10/30

Registrant information

Name

Sirus Pakseresht

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1338 3124

Email address

pakseresht@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of tricyclic antidepressant augmentation with herbal formation Hypericum perforatum and placebo in depressed outpatients referred to psychiatric clinic and Golestan hospital / Ahvaz /Iran

Public title

Therapeutic effect of herbal formulation Hypericum perforatum with antidepressant drug

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Major depressive disorder diagnosed by a psychiatrist based on DSM-IV-TR criteria, age range between 18-55 years, filling the consent form, mild or moderate severity of depression Exclusion Criteria: Pregnancy, breast feeding, organic or neurological disorder featuring both clinically, Axis II psychiatric disorder, presence of simultaneous psychiatric disorder

diagnosis in axis I, using alcohol and other addictive substances other than nicotine and caffeine in a one-month past, exacerbation of symptoms of severe depression or psychotic disorders, Signs that require hospitalization and emergency action such as suicidal thoughts and behaviors, Not receiving ECT over three months prior to the study, any particular sensitivity to plant grass herbal tea, consumption of medicine such as lithium, anticonvulsants, sumatriptan, Al Biped, serotonin-reuptake inhibitors, buspirone, Argo compounds, Selegiline, stimulants, anti-congestive, contraceptives, cimetidine, theophylline or thyroid hormones during 7 days prior to the study

Age
From **18 years** old to **55 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jundishapur Univercity of Medical Sciences
Street address
Golestan boulevard
City
Ahvaz
Postal code
Approval date
2010-04-18, 1389/01/29
Ethics committee reference number
339//20/8/پ

Health conditions studied

1

Description of health condition studied
Moderate depression
ICD-10 code
F32.1
ICD-10 code description
Moderate depressive episode

2

Description of health condition studied
Mild depression
ICD-10 code
F 32.0
ICD-10 code description
Mild depressive episode

Primary outcomes

1

Description
Improvement of sleep
Timepoint
3 weeks
Method of measurement
clinical interview

2

Description
improvement of apetite
Timepoint
3 weeks
Method of measurement
clinical interview

Secondary outcomes

1

Description
treatment of depression
Timepoint
3 weeks
Method of measurement
Beck Rating Scale for Depression

Intervention groups

1

Description
Tricyclic antidepressant with average dose, as well as Hypericum Perforatum (a herbal formulation), three times a day 6 weeks
Category
Treatment - Drugs

2

Description
Tricyclic antidepressant with average dose, as well as placebo, three times a day 6 weeks

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
psychiatric clinic
Full name of responsible person
Street address
City
Ahvaz

2

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Street address
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Mostafa Feghhi
Street address
Golestan Blv
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research, Ahvaz Jundishapur 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
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Zhale Nilsaz
Position
Psychiatric Assistant
Other areas of specialty/work
Street address
Unit 3, Number 9, East Elham St., Kianpars
City
Ahvaz
Postal code
Phone
+98 61 1333 8770
Fax
Email
drbabapour@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Sirus Pakseresht
Position
Psychiatric Professor Assistant
Other areas of specialty/work
Street address
Unit 5, Number 110, sixth St., Kianpars west
City
Ahvaz
Postal code
Phone
+98 61 1338 3124
Fax
Email
Pakseresht@ajums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Zhale Nilsaz
Position
Psychiatric Assistant
Other areas of specialty/work
Street address
Unit 3, Number 9, East Elham St., Kianpars
City
Ahvaz
Postal code
Phone
+98 61 1333 8770
Fax
Email
drbabapour@yahoo.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