Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of licorice (Glycyrrhiza glabra) versus placebo on increasing the efficiency of antipsychotics in women with chronic schizophrenia, a double-blind clinical trials

Protocol summary

Study aim

The aim of this study was to investigate the effect of adding licorice to the therapeutic drug of the female patients with schizophrenia.

Design

This study was a double-blind, controlled trial, 20 woman patients with schizophrenia were assigned in each group.For randomization, the permuted block randomization will be used with quadruple blocks, In order to apply the concealment in the randomization process, unique codes, which is generated by the software, will be used on the drug boxes.

Settings and conduct

All patients referred to Imam Khomeini Hospital of Ahvaz, Iran, were assigned randomly in one of the treatment regimens for 8 weeks,The patients should be in the active phase of the disease and met DSM-IV criteria for chronic schizophrenia

Participants/Inclusion and exclusion criteria

In this study, 20 woman patients with schizophrenia were assigned in each group . The patients should be in the active phase of the disease and The patients were within the age range of 18-60 years old and the drug regimen of risperidone (6 mg/day) and cetirizine (4 mg/day). Exclusion criteria included bipolar disorder, dysthymic disorder

Intervention groups

Intervention group: 20 women with schizophrenia (in active phase), each receive a daily dose of 380 milligrams of licorice tablets, risperidone (6 mg/day) and cetirizine (4 mg/day) for 8 weeks. Control group: 20 men and women with schizophrenia (in active phase), each receive a daily dose of 380 milligrams of placebo (containing lactose, cellulose and starch), which looks like to licorice tablets, risperidone (6 mg/day) and cetirizine (4 mg/day) for 8 weeks.

Main outcome variables

PANSS score (Positive and Negative Syndrome Scale)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111105008013N2**
Registration date: **2018-08-26, 1397/06/04**
Registration timing: **retrospective**

Last update: **2018-08-26, 1397/06/04**
Update count: **0**

Registration date

2018-08-26, 1397/06/04

Registrant information

Name

Amir Siahpoosh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3334 2197

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

2018-01-21, 1396/11/01

Actual recruitment end date

2018-02-19, 1396/11/30

Trial completion date

empty

Scientific title

Effect of licorice (Glycyrrhiza glabra) versus placebo on increasing the efficiency of antipsychotics in women with chronic schizophrenia, a double-blind clinical trials

Public title

effect liqurice in treatment of schizophernia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Active schizophrenia Met DSM-IV criteria for chronic schizophrenia Drug regimen of risperidone (6 mg/day), cetirizine (4 mg/day)

Exclusion criteria:

Bipolar disorder Borderline-schizotypal-Antisocial personality disorder Eating disorder Alcohol and drug (other than schizophrenia drugs) abuse in the past month Suicide or suicidal ideation History of neurologic and systemic disorders Thyroid dysfunction Administration of antidepressants and Anti-anxiety drugs Steroids (such as oral contraceptives) Use of MAO-I drugs Pregnancy and lactation

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com).

Blinding (investigator's opinion)

Double blinded

Blinding description

Unique codes, which is generated by the software, will be used on the drug boxes. By entering each individual into the study based on the produced sequence, the drug box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Road

City

Ahvaz

Province

Khouzestan

Postal code

6135733184

Approval date

2012-01-21, 1390/11/01

Ethics committee reference number

ETH-351 , http://behsan.ajums.ac.ir/webdocument/load.action?webdocument_code=1000&masterCode=33003165

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Positive symptoms; Negative symptoms; General psychopathological symptoms

Timepoint

Start intervention and a month later

Method of measurement

PANSS score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: one tablet of D-Reglis (IRAN DAROUK Co., Tehran, Iran) containing 380 mg of standardized dried licorice extract for 8 weeks and three times a day
Category
Treatment - Drugs

2

Description
Intervention group: Placebo (starch + sugar) for 8 weeks and three times a day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Imam Khomeini Hospital
Full name of responsible person
Amir Siahpoosh
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Amir Siahpoosh
Position
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Person responsible for updating data

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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
Only a part of the data will be shared
When the data will become available and for how long
The access period will be 6 months after the publication of the results
To whom data/document is available
The obtained data from current study will be available only for researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis
From where data/document is obtainable
Applicants can be contacted with corresponding author by e-mail
What processes are involved for a request to access data/document
Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month
Comments