

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

Email address

siahpoosh-a@ajums.ac.ir

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 liquorice in treatment of schizophrenia

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

Bist-o Chahr Metri St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohamad badavi

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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

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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