Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effects and side effects of the three drugs risperidone, quetiapine and olanzapine in the treatment of psychosis symptoms due to Shisheh

Protocol summary

Study aim

Comparison of the effects of risperidone, quetiapine and olanzapine in the treatment of Shisheh induced psychosis Disorder

Design

The clinical trial has three intervention groups, phase ۳ on 45 patients, a blind strain. Samples are selected by available methods.

Settings and conduct

A study will be conducted on the symptoms of psychosis caused by the use of Shisheh, and the samples will be selected from Razi Hospital in Tabriz and will be divided into three groups: Risperidone, Quetiapine and Elanzapine. Data will be measured once before treatment and after one month with demographic questionnaire, urine test, SCID semi-structured interview, PANSS positive and negative symptom scale, and Glasgow side effect scale. The study is of a blind type and the analysis of the data log will not know which group the sample is in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from Shisheh induced psychosis Disorder, not suffering from other psychiatric disorders, having informed consent, at least 18 years old
Exclusion criteria: Lack of history of mental disorders, epilepsy, brain trauma, unwillingness to continue cooperation, incomplete questionnaires

Intervention groups

Intervention group 1 includes patients with Shisheh induced psychosis Disorder who are treated with risperidone. Intervention group 2 includes patients with Shisheh induced psychosis Disorder who are treated with Quetiapine. Intervention group 3 includes patients with Shisheh induced psychosis Disorder who are treated with Olanzapine.

Main outcome variables

Main outcomes include treatment of psychotic symptoms, positive and negative symptoms associated with Shisheh use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160530028173N5**
Registration date: **2023-12-12, 1402/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-12, 1402/09/21**
Update count: **0**

Registration date

2023-12-12, 1402/09/21

Registrant information

Name

Salman Safikhanlou

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects and side effects of the three drugs risperidone, quetiapine and olanzapine in the treatment of psychosis symptoms due to Shisheh

Public title

Efficacy and side effects of risperidone, quetiapine and olanzapine in the treatment of Shisheh psychosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having criteria for glass-induced psychosis disorder based on DSM-5 (through clinical interview by psychiatrist). Treated with one of the antipsychotics risperidone, quetiapine and olanzapine No other psychiatric disorders Willingness of an individual or family (conscious consent) to participate in the study Minimum age 18 If you have a history of drug treatment for the above disorder, at least three weeks have passed since you stopped taking the drug

Exclusion criteria:

History of mental disorders History of epilepsy History of brain trauma Taking drugs other than target group treatment drugs Unwillingness of the patient or the family to continue cooperating in the study for any reason Incomplete questionnaires If a sample has other psychiatric disorders, including personality disorders, it will be excluded from the plan and will continue its routine treatment. Incidence of drug complications based on the AIMS scale

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

analyst of the data were not aware of which group (risperidone, quetiapine and olanzapine) the sample was. Of course each sample has an special code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-10-21, 1402/07/29

Ethics committee reference number

IR.TBZMED.REC.1402.535

Health conditions studied

1

Description of health condition studied

psychosis symptoms due to Shisheh

ICD-10 code

f15

ICD-10 code description

Other stimulant related disorders

Primary outcomes

1

Description

Positive Symptoms Severity

Timepoint

Before the intervention, one month after the intervention

Method of measurement

PANSS positive and negative symptom scale

2

Description

Negative Symptoms Severity

Timepoint

Before the intervention, one month after the intervention

Method of measurement

PANSS positive and negative symptom scale

Secondary outcomes

empty

Intervention groups

1

Description

Patients will receive risperidone from Sobhan company daily in the therapeutic range of 2 to 8 mg. The patient will be evaluated by demographic questionnaire, urine test, PANSS positive and negative symptom tools once before starting the treatment and again after one month (according to DSM 5). Patients will be evaluated for drug side effects in the second and fourth weeks using the AIMS scale. In case of drug side effects, the patient will be excluded from the study and will continue the drug treatment process separately. In this regard, the patient's medication will be tapered and discontinued and will be changed to other medications. The substitute person will be entered in place of the exited sample, according to the entry and exit criteria.

Category

Treatment - Drugs

2

Description

Patients will receive Quetiapine drug of Tadbir Kalai Jam company in the therapeutic range of 25 to 100 mg daily. The patient will be evaluated by demographic questionnaire, urine test, PANSS positive and negative symptom tools once before starting the treatment and again after one month (according to DSM 5). Patients will be evaluated for drug side effects in the second and fourth weeks using the AIMS scale. In case of drug side effects, the patient will be excluded from the study and will continue the drug treatment process separately. In this regard, the patient's medication will be tapered and discontinued and will be changed to other medications. The substitute person will be entered in place of the exited sample, according to the entry and exit criteria.

Category

Treatment - Drugs

3

Description

Patients will receive Soban's Elanzapine drug in the therapeutic range of 5 to 10 mg daily. The patient will be evaluated by demographic questionnaire, urine test, PANSS positive and negative symptom tools once before starting the treatment and again after one month (according to DSM 5). Patients will be evaluated for drug side effects in the second and fourth weeks using the AIMS scale. In case of drug side effects, the patient will be excluded from the study and will continue the drug treatment process separately. In this regard, the patient's medication will be tapered and discontinued and will be changed to other medications. The substitute person will be entered in place of the exited sample, according to the entry and exit criteria.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Arash Mohagheghi

Street address
Elgoli Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Hasan Soleimanpour

Street address
Tabriz University of Medical Sciences, Golgasht Street, Azadi Street

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salman_safikhanlou@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Arash Mohagheghi

Position
Associate Professor (Psychiatry)

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Roya Mohammadi

Position
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Person responsible for updating data

Contact

Name of organization / entity
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Salman Safikhanlou

Position
Clinical psychologiest

Latest degree
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Psychology

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salman_safikhanlou@yahoo.com

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
Individual data including primary outcomes (drug effects and side effects) of participants can be shared after de-identification.

When the data will become available and for how long
The information will be available after analyzing the data and compiling the articles from 2024/09/21.

To whom data/document is available
The data will be accessible to health community researchers.

Under which criteria data/document could be used
The data will be available for research purposes.

From where data/document is obtainable
The data will be available through the study guide Dr. Arash Mohagheghi.

What processes are involved for a request to access data/document
The data will be available by sending a message to Dr. Arash Mohagheghi at the email address mohaggheghi@yahoo.com within one month after sending the email.

Comments