

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

The effect of bumetanide on positive , negative and cognitive symptoms of schizophrenic patients

Protocol summary

Summary

Objectives : In this clinical trial , we want to investigate the effect of Bumetanide on positive, negative and cognitive symptoms of schizophrenic patients. Design: This study is a single-center double-blind placebo-controlled randomized longitudinal clinical trial. Sample size: 20 patients per group Blinding and randomization: Patient will randomly be divided to control and treatment groups that should participate in a double-blind study .Treatment group will take bumetanide 1mg/twice daily and control group will take placebo. Neither patients nor evaluators will not be inform about type of drugs, placebo or bumetanide. Criteria: inclusion criteria: (1) Diagnosis of schizophrenia at any subtype according to DSM-IV diagnosis an statistical manual of mental disorders, 4th edition (2) aged 20 to 70 years (3) disease duration for at least 3 years (4) had a total score of at least 70 on the positive and negative syndrome scale(PANSS) (5) had persistent negative or considerable cognitive symptoms, that are equivalent with at least 20 and 15 score on the negative and cognitive subscales of PANSS, respectively. Exclusion criteria were: patients with a (1) documented fluctuation in symptoms (2) uncontrollable significant conditions (3) As well as concurrent history of significant psychiatric (except schizophrenia), cardiovascular, renal, hepatic, convulsive disorders or substance abuse. Intervention: as we mentioned above, one group will take bumetanide 1 mg/ twice daily and control group will take same dose of placebo. Main outcome measure: Primary outcome measures: Two groups will be evaluate by PNASS, BPRS, before drug taking and 1,2 months after the drug taking and after one-month drug-free washout period. At the end, the data gathered from these four assessments will be compared. Secondary outcome measures: Two groups will be evaluate by AIMS (for side effect) before drug taking and 1,2 months after the drug taking and after one-month drug-free washout period. At the end, the data gathered from these four assessments will be

compared.

General information

Acronym

Bumetanide

IRCT registration information

IRCT registration number: **IRCT2014012616374N1**

Registration date: **2015-12-23, 1394/10/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-23, 1394/10/02

Registrant information

Name

Mohammad Reza Khodaie Ardakani

Name of organization / entity

University of Social Welfare & Rehabilitation Sciences

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Recruitment status

Recruitment complete

Funding source

University of social welfare &rehabilitation sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of bumetanide on positive , negative and cognitive symptoms of schizophrenic patients

Public title
The effect of bumetanide on schizophrenia patients

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: (1) Diagnosis of schizophrenia at any subtype according to DSM-IV diagnosis an statistical manual of mental disorders, 4th edition (2) aged 20 to 70 years (3) disease duration for at least 3 years (4) had a total score of at least 70 on the positive and negative syndrome scale(PANSS) (5) had persistent negative or considerable cognitive symptoms, that are equivalent with at least 20 and 15 score on the negative and cognitive subscales of PANSS, respectively. Exclusion criteria were: patients with a (1) documented fluctuation in symptoms (2) uncontrollable significant conditions (3) As well as concurrent history of significant psychiatric (except schizophrenia), cardiovascular, renal, hepatic, convulsive disorders or substance abuse.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
Ethis committee of university of social welfare&rehabilitation sciences
Street address

University of Social Welfare & Rehabilitation Sciences.
Koodakyar street, Velenjac
City
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Postal code
1985713834
Approval date
2014-02-01, 1392/11/12
Ethics committee reference number
Uswr.rec.1392.47

Health conditions studied

1

Description of health condition studied
schizophrenia
ICD-10 code
f20
ICD-10 code description
schizophrenia

Primary outcomes

1

Description
Negative, positive and cognitive symptoms of schizophrenic patients
Timepoint
Before treatment and 1, 2 months after treatment and following one-month drug-free washout period
Method of measurement
PANSS and BPRS inquiries

Secondary outcomes

1

Description
Side effect
Timepoint
at assessment interviews; before treatment and 1,2 months after treatment and after one-month drug-free washout period
Method of measurement
AIMS test and clinical observation

Intervention groups

1

Description
Control group: take placebo . tab per day . Oral during 3months
Category
Treatment - Drugs

2

Description

Intervention group: take Bumetanide(Made in Belgium)
as an adjuvant therapy - made in Belgium Tab , 1mg
twice daily. Oral. During 2months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

RAZI Psychiatric Hospital

Full name of responsible person

Dr. Mohammad Reza Khodaie Ardakani

Street address

RAZI Psychiatric Hospital, Amin abad, shahre Rey

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, university of Social
Welfare & Rehabilitation sciences

Full name of responsible person

Hamidreza Khanke

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City

Tehran

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, university of Social Welfare
& Rehabilitation 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

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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