Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Description and comparison of autonomous nervous system function in aggressive depressed patients before and after serteralin treatment by the measurement of related biomarkers

Protocol summary

Summary

The object of the study, is the description and comparison of autonomous nervous system function in aggressive depressed patients before and after treatment by serteraline. Among visited patients at Psychology clinic of Razi Hospital in Tabriz, 50 patients who suffer from depression, are selected with the conditions of being in their first episode of disease, and no history of anti-depressive medical treatment. Throughout two questionnaire, "SCID" and "Beck", degree of depression and by questionnaire of "STAXI-2", degree of aggression are scored, then bio-markers' basic condition such as heart rate, blood pressure, respiratory rate, etc ... through a Biofeedback system are evaluated. In the next step, seteraline (Asentra) starts with initial dose of 50 mg per day (which could be raised to 100 mg per day), and at the intervals of 1.5 and 3 months, bio-markers are re-evaluated to compare the function of autonomous system with the basic states. If it confirmed that autonomous system function are abnormal in aggressive depressive patients, and after the treatment with Asentra, it becomes normalized, a common etiology could be propounded, so that autonomous modifier drugs for patients who are irresponsible to routine treatments may be suggested.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411122999N4**
Registration date: **2015-07-10, 1394/04/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-10, 1394/04/19

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source
Tabriz University Of Medical Sciences

Expected recruitment start date
2015-03-21, 1394/01/01

Expected recruitment end date
2015-09-23, 1394/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Description and comparison of autonomous nervous system function in aggressive depressed patients before and after serteralin treatment by the measurement of related biomarkers

Public title
Effect of serteraline in depressed aggressive patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Depression should be confirmed by a psychologist throughout a structured interview based on DSM-IV criteria; Patient should be at 1st episode of disease, with no history of anti-depression treatment (medical or non-medical); Presence of aggressive behaviors confirmed by history or medical examination; Patient prefers taking more efficient drug, no matter how expensive; Iranian nationality; Age between 20 to 40 years old; Agreement for participating in study through signing testimonial form Exclusion criteria: History of any psychological disease, except for depression; Present history of any drug affecting CNS/PNS; History of any of these conditions: Amyloidosis, Acute porphyria, Cardiovascular/Respiratory/Endocrine/Neurologic disease, Alcohol/drug abuse, Malabsortion, Multiple sclerosis, ALS; Pre-menstural syndrome for female; Presence of genetical susceptibility to above mentioned conditions

Age

From **19 years** old to **39 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Present study is of "Before after study" type.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University Of Medical Sciences

Street address

Central building No. 2, Tabriz University Of Medical Science, Golgasht street, Tabriz

City

Tabriz

Postal code

Approval date

2015-03-09, 1393/12/18

Ethics committee reference number

93196

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.9

ICD-10 code description

Depression NOS

Primary outcomes

1

Description

Depression intensity

Timepoint

1.5

Method of measurement

Beck Questionnaire, 2nd edition

2

Description

Anger status

Timepoint

1.5

Method of measurement

STAXI Questionnaire, 2nd edition

3

Description

Heart rate variability

Timepoint

1.5

Method of measurement

Biofeedback system

4

Description

Respiratory Rate

Timepoint

1.5

Method of measurement

Biofeedback system

5

Description

Heart rate

Timepoint

1.5

Method of measurement

Biofeedback system

6

Description
Skin Temprature
Timepoint
1.5
Method of measurement
Biofeedback system

7

Description
Blood Pressure
Timepoint
1.5
Method of measurement
Biofeedback system

8

Description
Valsalva Ratio
Timepoint
1.5
Method of measurement
Biofeedback system

9

Description
Expiratory:Inspiratory ratio
Timepoint
1.5
Method of measurement
Biofeedback system

10

Description
Skin conductivity level
Timepoint
1.5
Method of measurement
Biofeedback system

Secondary outcomes

empty

Intervention groups

1

Description
At first, the patients are scored by "Beck" 2nd edition questionnaire and "Structured Clinical Interview-DSM-IV (SCID) for severity of depression, and also by "State-Trait Anger Expression Inventory-2" questionnaire (STAXI-2) for the state of aggression. Afterwards, basic states of biomarkers, including heart rate, blood pressure, respiratory rate and etc... will be measured by a bio-feedback system. Then medical treatment with serteraline (Asentra, manufactured by ACTOVERCO factory, Karaj, Iran) by initial dose of 50 mg /day, orally, starts. The dosage could raise to 100 mg/day if weekly visits indicate that clinical response is inappropriate. At the intervals of 1.5 and 3 months later, autonomous biomarkers will be re-evaluted to compared with the basic states.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Arezoo Mehrara
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University Of Medical Science
Full name of responsible person
Sarvar Alipour
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Research Division, 3rd Floor, Central Building No.2, Golgasht Ave. Azadi st.
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Grant name
Grant code / Reference number
no
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University Of Medical Science
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

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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