Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of effectiveness of Sertraline and supportive psychotherapy on anxiety and depression level of Leukemia patient referring to clinic of Ali-ibn-Abitaleb Hospital in Zahedan

Protocol summary

Study aim

The comparison between the effect of Sertraline and supportive psychotherapy on the anxiety and depression of the patients with definite diagnosis of leukemia

Design

Two arm parallel groups randomized trial without blindness

Settings and conduct

This study will be performed in Imam Ali clinic at Zahedan. 60 patients who were administered with the definite diagnosis of leukemia by the specialist and age domain of 18 to 64 years old will be included in our study. one group will be treated by the supportive psychotherapy session for 6 weeks and the other group will be treated by Sertraline. the rate of anxiety and depression will be evaluated y the anxiety and depression questionnaire of Hamilton at the beginning of the treatment, first, third, sixth week after the treatment.

Participants/Inclusion and exclusion criteria

The patients with the definite diagnosis of leukemia and the age domain of 18 to 64 years without any history of previous medical and psychological problems will be included to our study and the patients with the allergy to Sertraline or dissatisfaction will be excluded from the study.

Intervention groups

The first intervention group includes 30 patients who will be treated by supportive psychotherapy session with the duration of each about 90 minutes for 6 weeks and the second intervention group will be treated by the first therapeutic dose of 50 mg of Sertralin which will be increased to 200mg in two weeks due to the lack of response

Main outcome variables

Age, gender, rate of anxiety, rate of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180425039418N4**
Registration date: **2019-01-25, 1397/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-25, 1397/11/05**
Update count: **0**

Registration date

2019-01-25, 1397/11/05

Registrant information

Name

mohammad Ghena'at Pisheh Sanani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3343 1227

Email address

mohammad.ghenaat71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of effectiveness of Sertraline and supportive psychotherapy on anxiety and depression level of Leukemia patient referring to clinic of Ali-ibn-Abitaleb Hospital in Zahedan

Public title
Evaluation of effectiveness of Sertraline and supportive psychotherapy on anxiety and depression level
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The age range of patients is between 18 to 64 years old The patients were administered with the definite diagnosis of leukemia by the specialist All the patients should fill up the written consent and give it to the researchers for attending the study The education level of the patients is at least from elementary The patients don't have any history of other medical or psychological disorders The patients don't have any history of drug consumption except smoking
Exclusion criteria:
The patient doesn't intend to attend the study The patient has a history of allergy to Sertraline
Age
From **18 years** old to **64 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The simple randomization that the patients with the definite diagnosis of leukemia who referred to the clinic of Ali-Ibn-Abitaleb Hospital, will be classified into two groups each with 30 people by the
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Dr.Hesabi Square, Campus of Medical Scineces
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2017-09-24, 1396/07/02
Ethics committee reference number
IR.ZAUMS.REC.1397.326

Health conditions studied

1

Description of health condition studied
Major depression disorders
ICD-10 code
F33.9
ICD-10 code description
Major depressive disorder, Recurrent, Unspecified

2

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
The Scale of Questionnaire on Hamilton's Depression and Anxiety
Timepoint
At the time of beginning of therapies, 1 week after beginning the therapies , 3 weeks after beginning the therapies , and 6 weeks after beginning the therapies
Method of measurement
The Scale of Questionnaire on Hamilton's Depression and Anxiety

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In this group, 30 patients with the definite diagnosis of leukemia with the age range of 18 to 64 years old at the clinic of Ali-ibn-Abitaleb Hospital in Zahedan, will treated with the administration of the

first dose of 50 mg Sertraline. However, the dosage will be increased to 200mg daily due to the lack of response

Category

Treatment - Drugs

2

Description

Second intervention group: In this group, 30 patients with definite diagnosis of Parkinson disease and age domain of 18 to 64 years old at the clinic of Ali-ibn-Abitaleb Hospital in Zahedan, will be treated by 6 weeks supportive psychotherapy in which each session has the duration of 90 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ibn-Abitaleb Hospital (as)

Full name of responsible person

Amirali Fani

Street address

Salamat Blvd, Persian Gulf Expressway

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

it@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohammad Hashemi

Street address

Dr.Hesabi square , Medical Sciences Campus

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Sistan-va-Balouchestan

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9816743463

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Email

public@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Amirali Fani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no information yet
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available