

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of sertraline effects on the time of engraftment and serum levels of such inflammatory and anti-inflammatory factors as IL-6, CRP and IL-10 in depressed HSCT patients

Protocol summary

Summary

The main aim of this study is to evaluate the effect of sertraline on the time of engraftment as well as the anti-inflammatory effect of sertraline in depressed or anxious patients undergoing Hematopoietic stem cell transplantation (HSCTs) . To this aim, forty adult patients with depression or anxiety based on the initial diagnosis by psychiatric and also the results of the filled in questionnaire of Hospital Anxiety & Depression Scale (HADS) are randomized to receive sertraline (100 mg orally once daily) (n =20) or placebo (n = 20) for 3 month duration. Blood sampling are performed at baseline (before starting sertraline) and 4 and 8 weeks after sertraline and placebo treatment. Inflammatory and anti-inflammatory cytokines such as IL-6 (Interleukin 6) and IL-10 (Interleukin 10) and also hs-CRP (high sensitivity C-reactive protein) are measured for all patients. Also after beginning the treatment in weeks 2, 4, 8 and 12 anti-depression response to treatment again will be evaluated using HADS questionnaire. Furthermore, to evaluate the effect of sertraline on the time of engraftment, white blood cell (WBC) and platelet will be recorded daily after transplantation until engraftment. Adverse outcomes and complications induced by medications and transplantation such as nausea , vomiting , mucositis ,VOD (veno-occlusive disease) , seizure and aGVHD (acute graft-versus-host disease) after transplantation will be evaluated too. Demographic & clinical data including the underlying disease that has led to transplantation , current medications, the most recent laboratory values and co-morbidities are obtained from the patient's medical records.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310083210N4**

Registration date: **2013-12-11, 1392/09/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-11, 1392/09/20

Registrant information

Name

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Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences Tehran
Iran Iran, Islamic Republic Of

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of sertraline effects on the time of engraftment and serum levels of such inflammatory and anti-inflammatory factors as IL-6, CRP and IL-10 in depressed HSCT patients

Public title

Evaluation of sertraline in depressed or anxious HSCT patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 to 60 years for allo-HSCT and auto-HSCT; presence of depression or based on Hospital Anxiety & Depression Scale (HADS) ; Stable & normal renal and liver function and ; Ability for oral taking of medication . Exclusion criteria: Patients with baseline kidney dysfunction (GFR less than 60 mL/min) ;Patients with abnormal LFT (bilirubin & aminotransferases level of more than 2 normal) ; Patient with sepsis or uncontrolled infection at baseline ; Patients unable to take orally ; Non-cooperable patients with mental dysfunctionality ; pregnant or lactating women ; HIV+ patients ; Patients who have taken antidepressant medication later than a month ago ;Intolerance of Sertraline adverse effects.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Shahid Behesti University Of Medical Sciences

Street address

Valiasr street

City

Tehran

Postal code

0098

Approval date

2013-10-29, 1392/08/07

Ethics committee reference number

253

Health conditions studied

1

Description of health condition studied

Depression and anxiety

ICD-10 code

F32,F41.1

ICD-10 code description

Depressive episode,Generalized anxiety disorder

Primary outcomes

1

Description

Depression

Timepoint

Baseline 2 ,4, 8 and 12 weeks after

Method of measurement

Hospital Anxiety and Depression Scale (HADS) questionnaire

2

Description

Anxiety

Timepoint

Baseline 2 ,4, 8 and 12 weeks after

Method of measurement

Hospital Anxiety and Depression Scale (HADS) questionnaire

3

Description

IL-10 Inflammatory biomarker

Timepoint

Baseline, 2 and 4weeks after

Method of measurement

serum level pg/ml

4

Description

IL-6 inflammatory biomarker

Timepoint

Baseline, 4 and 8 weeks after

Method of measurement

Serum level pg / mL

5

Description

Hs-CRP inflammatory biomarker

Timepoint

Baseline, 4 and 8 weeks after

Method of measurement

Serum level mg / dl

Secondary outcomes

1

Description

engraftment time

Timepoint

Daily until absolute neutrophil count (ANC) more than 500 and platelet more than 20000 for 3 consecutive days

Method of measurement

Cell blood count(CBC)

Intervention groups

1

Description

Control group: Placebo 50 to 100 mg orally per day for 90 days

Category

Placebo

2

Description

Intervention group: sertraline 50 to 100mg orally per day for 90 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bone Marrow Transplantation center of Tehran
Taleghani Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of pharmacy,Research of deputy ,Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Shams

Street address

Valiasr

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of pharmacy,Research of deputy ,Shahid Beheshti University Of Medical 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Mehrpooya

Position

PharmD, Resident of Clinical Pharmacy

Other areas of specialty/work

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Tehran

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