Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of sertraline effects on the time of engraftmen 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

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Name of organization / entity
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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 engraftmen 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-cooporable patients with mental dysfunctionality ; pregnant or lactating women ; HIV+ patients ; Patients who 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 Inflammatort 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

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Full name of responsible person

Maryam Mehrpooya

Position

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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