

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the effect of Melatonin on the stem cells collection and engraftment in autologous hematopoietic stem cells transplant recipients

Protocol summary

Study aim

Evaluation of the Effectiveness of Melatonin on engraftment and Stem Cell Collection in Patients Undergoing autologous Bone Marrow Transplant (ABMT)

Design

A randomized triple blind clinical trial with a parallel group design of 48 patients, undergoing ABMT

Settings and conduct

This study perform at BMT ward of Ayatollah Taleghani Teaching Hospital in a randomized, triple blind (patient, physician and researcher) in two groups of drug and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria contain: 1. Age between 18 to 70 years 2. Malignancy diagnosis according oncologist specialist 3. Non-pregnancy and lactation 4. Informed consent to participate in the study Exclusion criteria contain: 1. Not using Melatonin or placebo for three doses Consecutively 2. Unable to keep sublingual tablets under the tongue 3. Taking more than 2 sedative or hypnotic medicine (example: Benzodiazepines) regularly over a week

Intervention groups

In the intervention group, patients receive Melatonin (manufactured by Vana Daru Gostar) along with the G-CSF protocol. The administration of Melatonin starts 5 days prior to cell collection with dose of 3 mg twice daily concomitant with G-CSF, then 9 mg 30 minutes prior to cell collection and finally twice daily dose of 3 mg sublingual until engraftment. In the Control group, patients receive placebo along with the G-CSF protocol. The administration of placebo starts 5 days prior to cell collection with dose of one tablet twice daily concomitant with G-CSF, then 3 tablet 30 minutes prior to cell collection and finally twice daily dose of one tablet sublingual until engraftment.

Main outcome variables

Evaluation of CD34 changes, Engraftment duration, Dose requirement of G-CSF, Sleep disturbance according to Insomnia Severity Index (ISI), Anxiety Score according to

Hospital Anxiety and Depression Scale (HADS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N20**

Registration date: **2020-02-20, 1398/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-20, 1398/12/01**

Update count: **0**

Registration date

2020-02-20, 1398/12/01

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaheed Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

maria.tavakoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-05, 1398/08/14

Expected recruitment end date

2020-11-04, 1399/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Melatonin on the stem cells collection and engraftment in autologous hematopoietic stem cells transplant recipients

Public title
Effect of Melatonin on autologous hematopoietic stem cells transplant success

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of malignancy according to expert opinion and Laboratory data Fill in the Consent Ages 18-70 years
Exclusion criteria:
Not using of Melatonin for 3 doses consecutive Inability to use sublingual tablets Taking more than 2 sedative or hypnotic medicine (example: Benzodiazepines) regularly over a week

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we use Cluster block randomization method by online statistical software. So, we have 8 blocks with block size 6, that 3 participants receive Melatonin and the others receive placebo. The allocation and distribution of blocks are done and a code is generated for each sample by online software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, participants, principle investigator initiated trials, healthcare providers (Physicians and Nurses), data collectors, outcome assessors are unaware of the study groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Pharmacy and Nursing & Midwifery - Shahid Beheshti University of Medical Sciences

Street address

Faculty of Pharmacy, Niayesh intersection, Valiasr Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-11-04, 1398/08/13

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.214

Health conditions studied

1

Description of health condition studied

Autologous Hematopoietic Stem Cells Transplant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

CD34 changes

Timepoint

Daily

Method of measurement

Blood sample and use a Laboratory Kit

2

Description

Engraftment duration

Timepoint

Daily

Method of measurement

Blood sample

3

Description

GCSF dose requirement

Timepoint

Daily

Method of measurement

Dose requirement according physician orders

Secondary outcomes

1

Description

Sleep disturbance during transplant

Timepoint

Weekly

Method of measurement

Insomnia Severity Index (ISI)

2

Description

Anxiety score during transplantation

Timepoint

Weekly

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

Intervention groups

1

Description

In the intervention group, patients receive Melatonin (manufactured by Vana Daru Gostar) along with the G-CSF protocol. The administration of sublingual Melatonin starts 5 days prior to cell collection with dose of 3 mg twice daily concomitant with G-CSF, then 9 mg sublingual 30 minutes prior to cell collection and finally twice daily dose of 3 mg sublingual tablet until engraftment.

Category

Treatment - Drugs

2

Description

In the Control group, patients receive placebo along with the G-CSF protocol. The administration of placebo starts 5 days prior to cell collection with dose of one sublingual tablet twice daily concomitant with G-CSF, then 3 sublingual tablets 30 minutes prior to cell collection and finally twice daily dose of one sublingual tablet until engraftment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Maria Tavakoli Ardakani

Street address

Velenjak St., Shahid Chamran Highway., Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 9982

Email

Taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Yemen St., Velenjak Str., Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maria Tavakoli Ardakani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Clinical Pharmacy

Street address

Faculty of Pharmacy, Shahid Beheshti University of Medical Science, Valiasr St., Niayesh intersection., Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 8820 0085

Email

Mariatavakoli@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maria Tavakoli Ardakani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

clinical pharmacy

Street address

Faculty of Pharmacy, Shahid Beheshti University of Medical Science, Niayesh Intersection, Valiasr St., Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 8820 0085

Email

mariatavakoli@sbmu.ac.ir

Web page address

<https://pharmacy.sbmu.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Neda Kazeminiya

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Clinical Pharmacy

Street address

Faculty of Pharmacy, Shahid Beheshti University of Medical Science, Niayesh Intersection, Vlieasr St.,Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 2261 3871

Email

n.kazeminiya@gmail.com

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

Information are confidential

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

Undecided - It is not yet known if there will be 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