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 contian: 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) regulary 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-CSG, Sleep disturbance according to Insomnia Severity Index (ISI), Anxeity 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
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Name of organization / entity
Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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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) regulary 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

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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
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Velenjak St., Shahid Chamran Highway., Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

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Latest degree

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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

فا 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