

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of continuing care model on complications of bone marrow transplantation in patients undergoing bone marrow transplantation

Protocol summary

Study aim

Defining the effect of continuing care model on complications of bone marrow transplantation in patients undergoing bone marrow transplantation.

Design

In this study, 104 patients with leukemia and study entry conditions who are referred to the Center for Transplantation of Stem Cells at Shariati Hospital in Tehran are selected. In this study, the method used to generate random sequences of patients in the control and case groups is done by stratified randomization. Randomizing at the individual level. By categorizing effective variables such as age, gender, type of transplant, etc., before random assignment, we try to eliminate heterogeneity in groups. Then each randomization class is based on blocking. Allocating patients in the two groups will done randomly on the basis of two blocks. Sequence according to the number of samples in each group, in general 26 blocks.

Settings and conduct

The study is a clinical trial, two groups, parallel and without blindness in order to defining the effect of continuing care model on complications of bone marrow transplantation in patients undergoing bone marrow transplantation. The study population includes all patients that undergoing stem cell transplantation in the center of bone marrow transplantation at Shariati Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient is undergoing stem cell transplantation, Satisfaction of the patient to participate in the study, Have at least reading and writing skills, Age between 15 and 60 years. : Exclusion criteria: Patients with major thalassemia or immunodeficiency disorders, Lack of access to methods of communication such as telephone, The patient is a member of the treatment team. verbal, perceptual and psychological disorders

Intervention groups

We use a continuous care model in the education of

transplanted patients. The control group will receive routine care and routine training, and Patients in the intervention group will receive routine care, continuing education in order to improve nutrition, relieve the symptoms and complications of Graft versus host disease, control infection and reduce the days of admission and anxiety control on an individual and face-to-face basis, based on a continuous care model for 3 months

Main outcome variables

Consequences such as the number of hospital days, degree of oral mucositis, Graft versus host disease grade, clinical and laboratory signs and symptoms of infection, and severity of anxiety are measured every 4 weeks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170923036337N2**

Registration date: **2018-02-02, 1396/11/13**

Registration timing: **retrospective**

Last update: **2018-02-02, 1396/11/13**

Update count: **0**

Registration date

2018-02-02, 1396/11/13

Registrant information

Name

Fatemeh Esmailzadeh

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Email address fatemeh.esmaielzadeh@yahoo.com	number of samples in each group, in general 26 blocks. Method of allocation concealment is Central randomization.
Recruitment status Recruitment complete	Blinding (investigator's opinion) Not blinded
Funding source Vice chancellor for research, Tehran University of Medical Sciences	Blinding description Placebo Not used
Expected recruitment start date 2017-07-23, 1396/05/01	Assignment Parallel
Expected recruitment end date 2018-01-20, 1396/10/30	Other design features
Actual recruitment start date empty	Secondary Ids empty
Actual recruitment end date empty	Ethics committees
Trial completion date empty	1
Scientific title The effect of continuing care model on complications of bone marrow transplantation in patients undergoing bone marrow transplantation	Ethics committee Name of ethics committee Ethics Committee of the Faculty of Nursing and Midwifery and Rehabilitation, Tehran University of M
Public title The Effect of Continuous Care Model On the Bone Marrow Transplantation Complications	Street address Faculty of Nursing and Midwifery, Nosrat Sharghi Street, Tohid Square, Tehran
Purpose Other	City Tehran
Inclusion/Exclusion criteria Inclusion criteria: Have at least reading and writing skills, Age between 15 and 60 years, Lack of verbal and perceptual and psychological disorders The patient should not be simultaneously in another study Exclusion criteria: The patient is a member of the treatment team, Incidence of intense complications after bone marrow transplantation Relapse of disease Death of Patient	Province Tehran
Age From 15 years old to 60 years old	Postal code 1419733171
Gender Both	Approval date 2017-02-07, 1395/11/19
Phase 3	Ethics committee reference number کد طرح / IR.TUMS.FNM.REC.1395.1670 : شماره نامه 9411698002:
Groups that have been masked <i>No information</i>	Health conditions studied
Sample size Target sample size: 104	1
Randomization (investigator's opinion) Randomized	Description of health condition studied aplastic anaemia
Randomization description In this study, the method used to generate random sequences of patients in the control and case groups is done by stratified randomization. Randomizing at the individual level. By categorizing effective variables such as age, gender, type of transplant, etc., before random assignment, we try to eliminate heterogeneity in groups. Then each randomization class is based on blocking. Allocating patients in the two groups will done randomly on the basis of double blocks. Sequence according to the	ICD-10 code D61
	ICD-10 code description Other aplastic anaemias
	2
	Description of health condition studied Multiple myeloma
	ICD-10 code C90
	ICD-10 code description Multiple myeloma
	3
	Description of health condition studied

Hodgkin lymphoma

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

4

Description of health condition studied

non-Hodgkin lymphoma

ICD-10 code

C85

ICD-10 code description

Other and unspecified types of non-Hodgkin lymphoma

5

Description of health condition studied

Lymphoblastic leukemia

ICD-10 code

C91

ICD-10 code description

Lymphoid leukaemia

6

Description of health condition studied

Myeloblastic leukemia

ICD-10 code

C92

ICD-10 code description

Myeloid leukaemia

Primary outcomes

1

Description

Graft-Versus-Host Disease (GVHD)

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

GVHD grading using the Glucksberg grade scale

2

Description

Oral mucositis

Timepoint

Before Stem Cell Transplantation and every 4 weeks for the first 3 months after transplantation

Method of measurement

WHO Oral Mucositis Grading Scale

3

Description

The rate of re-admission related to stem cell transplantation

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

the number of days that patient admit in the post-

transplant stem cell care unit

4

Description

Signs and symptoms of infection

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Clinical examination and symptom registration

5

Description

Anxiety

Timepoint

Before Stem Cell Transplantation and every 4 weeks for the first 3 months after transplantation

Method of measurement

The State-Trait Anxiety Inventory and VAS Tool

Secondary outcomes

1

Description

The main reason for re-admission

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Readmission Questionnaire

2

Description

Days of readmission

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Readmission Questionnaire

3

Description

Types of treatments performed on re-admission

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Readmission Questionnaire

4

Description

skin graft-versus-host disease

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

GVHD grading using the Glucksberg grade scale

5

Description

gastrointestinal graft-versus-host disease

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

GVHD grading using the Glucksberg grade scale

6

Description

Hepatic graft-versus-host disease

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

GVHD grading using the Glucksberg grade scale

7

Description

Fever

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Clinical examination and symptom registration

8

Description

Shivering

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Clinical examination and symptom registration

9

Description

Dysuria

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Clinical examination and symptom registration

10

Description

Airway secretions

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Clinical examination and symptom registration

11

Description

The cytomegalovirus (CMV) status

Timepoint

Every 4 weeks for the first 3 months after transplantation

Method of measurement

Using real time PCR (copies/mL)

Intervention groups

1

Description

In the intervention group: In this intervention study, a continuous care model was used to educate patients undergoing stem cell transplantation. After collecting information at the first time (in the clinic) for each patient, based on the Inclusion criteria, they will be inter the study from the first day of admission for transplantation. Patient in the case group, in addition to routine care and training, will receive training based on a continuous care model, which is a native care model with specific continuity and coherence, for 3 months. During 3 individual and face-to-face sessions, this group will receive a training booklet includes training bone marrow and stem cell transplantation, chemotherapy, Complications of chemotherapy, recommendations for the prevention and control of chemotherapy complications, post-bone marrow transplant care and post- Stem cells transplant interventions to transplant patients. The researcher uses the framework of a continuous care model that includes the stages of Orientation, sensitization, control and evaluation. In the Orientation stage, new care issues are identified, categorized and reviewed. In the second phase, individually continuous training is provided on improving nutrition, relieving the symptoms and complications of GVHD, controlling infection, reducing the number of admission days and anxiety control. And in the third step, by consulting and referring patients for a visit, their questions will be answered and a booklet containing the training will be given to them. In the fourth stage, by phone or face to face, the implementation of the care model plan is followed up. Follow-Up times are in the first month, the second month and then the third month after transplantation. At this time, the questionnaires are completed again and their information is compared.

Category

Other

2

Description

In the control group: Patients will receive the same routine care and routine training by nurses in the transplant department, just in the same hospital stay.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital, Tehran

Full name of responsible person

Fatemeh Esmailzadeh

Street address

Dr. Shariati Hospital, Amir Abad, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Dr. Masood Younesian
Street address
Central building of Tehran University of Medical Sciences, Qhds street, Keshavarz Blvd, Tehran
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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

Vice chancellor for research of Tehran 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
Faculty of Nursing and Midwifery, Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Esmaielzadeh
Position

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Person responsible for updating data

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Web page address**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

I have not decided yet. The release plan is still unknown

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available