Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Esmaielzadeh

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date
2017-07-23, 1396/05/01
Expected recruitment end date
2018-01-20, 1396/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
The Effect of Continuous Care Model On the Bone Marrow Transplantation Complications
Purpose
Other
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
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **104**
Randomization (investigator's opinion)
Randomized
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 number of samples in each group, in general 26 blocks. Method of allocation concealment is Central randomization.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Nursing and Midwifery and Rehabilitation, Tehran University of M
Street address
Faculty of Nursing and Midwifery, Nosrat Sharghi Street, Tohid Square, Tehran
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2017-02-07, 1395/11/19
Ethics committee reference number
شماره نامه : IR.TUMS.FNM.REC.1395.1670 / کد طرح 9411698002:

Health conditions studied

1

Description of health condition studied
aplastic anaemia
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 Esmaielzadeh
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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
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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
Master of Nursing
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Master
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Person responsible for updating data

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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

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