Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Benson relaxation effect on fatigue level in patients after hematopoietic stem Cell transplant.

Protocol summary

Summary

This randomized clinical trial will be conducted on 40 patients undergoing stem cell transplantation in Amir Kola Children’s hospital in Babol. Inclusion criteria included age older than 18 years; diagnosed with multiple myeloma; leukemia and lymphoma; lack of neuromuscular disorders; lack of sedation assumption; no history of Benson relaxation; Stem cell transplantation for the first time; Exclusion criteria included serious physical complaints such as severe infection; severe pain and acute bleeding; loss of consciousness; the fourth-grade graft versus host disease. After approving of the study by sciences vice chancellor of Mazandaran University of medical sciences and completing of written consent form by all participants in the study, Patients will be divided randomly into two equal groups: 20 patients in experimental and 20 in control group. Demographic questionnaire and Brief Fatigue Inventory (BFI) will complete by all patients on admission day. The experimental group will receive supportive intervention One day after admission and get education of Benson relaxation with video tape and every patient will get one CD and pamphlet for use in Bone Marrow Transplantation unit. Patients in experimental group will do Benson relaxation for 20 minute, twice a day during fifteen days from the stem cell transplant day in the intervention group. No intervention will be made in control group. Brief Fatigue Inventory (BFI) will complete by all patients eight days and two weeks after the transplant after intervention. In cases that the patients can't able to read or write, the researcher will complete the questionnaire based on exact patient's statements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091624047N1**

Registration date: **2015-12-13, 1394/09/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-13, 1394/09/22

Registrant information

Name

Hedayat Jafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 7268

Email address

hjafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2015-09-07, 1394/06/16

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Benson relaxation effect on fatigue level in patients after hematopoietic stem Cell transplant.

Public title

Relaxation effect on fatigue in patients after stem cell transplant.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria included age older than 18 years; diagnosed with multiple myeloma; leukemia and lymphoma; lack of neuromuscular disorders; lack of sedation assumption; no history of Benson relaxation; Stem cell transplantation for the first time; Exclusion criteria included serious physical complaints such as severe infection; severe pain and acute bleeding; loss of consciousness; the fourth-grade graft versus host disease.

Age

From **18 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)

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 Mazandaran University of Medical Science

Street address

Moalem Street, Moalem Square, Sari

City

Sari

Postal code

4815696869

Approval date

2015-09-06, 1394/06/15

Ethics committee reference number

IR.MAZUMS.REC.94

Health conditions studied

1

Description of health condition studied

Patients receiving hematopoietic stem cells

ICD-10 code

c81-c96

ICD-10 code description

Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue

Primary outcomes

1

Description

Fatigye

Timepoint

Admission time, 8 days after transplantation and 2 weeks after transplantation

Method of measurement

Brief Fatigue Inventory

Secondary outcomes

empty

Intervention groups

1

Description

After approving of the study by sciences vice chancellor of Mazandaran University of medical sciences and completing of written consent form by all participants in the study, Patients will be divided randomly into two equal groups: 20 patients in experimental and 20 in control group. Demographic questionnaire and Brief Fatigue Inventory (BFI) will complete by all patients on admission day. The experimental group will receive supportive intervention One day after admission and get education of Benson relaxation with video tape and every patient will get one CD and pamphlet for use in Bone Marrow Transplantation unit. Patients in experimental group will do Benson relaxation for 20 minute, twice a day during fifteen days from the stem cell transplant day in the intervention group. Brief Fatigue Inventory (BFI) will complete by all patients eight days and two weeks after the transplant after intervention. In cases that the patients can't able to read or write, the researcher will complete the questionnaire based on exact patient's statements.

Category

Behavior

2

Description

No intervention will be made in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
AmirKola Chidren's hospital

Full name of responsible person
Somayeh Hassanpour

Street address
Non-Communicable Pediatric Diseases Research Center, Babol Univercity of Medical Sciences,Babol, IR Iran

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research Mazandaran University of Medical Sciences.

Full name of responsible person
Dr. Ahmahali Enayati

Street address
Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street ,Moalem Square,Sari, Iran.

City
Sari

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 Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Somayeh Hassanpour

Position
MSC in critical care nursing

Other areas of specialty/work

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School of Nursing & Midwifery Mazandaran University of Medical Sciences, Vessal Street Sari, Iran.

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Person responsible for scientific inquiries

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Position
Assistant Professor, scientific committee

Other areas of specialty/work

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Person responsible for updating data

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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