Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Comparing the effect of family-centered supportive program and routine care on chemotherapy complications among leukaemia patients

Protocol summary

Study aim
The Effect of family-focused supportive program on chemotherapy complications of leukemia patients

Design
The study will have intervention group (30 patient- at Shariati Hospital) and control group (30 patients-at Taleghani hospital). In each hospital the sampling will be Convenience. Allocation to the groups will be done non randomly.

Settings and conduct
Chemotherapy wards of Shariati andTaleqani hospitals will form the field.Patients and their families in the intervention group will be monitored for up to three months while being under consolidation chemotherapy. In each session of chemotherapy the type, severity and discomfort of chemotherapy will be determined. In this study, only the statistician blinding will be performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria for patients: age over 18 years old; referring to chemotherapy clinic and receive the first or second consolidation chemotherapy. Inclusion criteria for patients' relatives: age between 18 to 60 years old; being the first people of patient; giving care to patient at home; and obedience by patient. Non-inclusion criteria for patients: having a history of chemotherapy in family member. Non-inclusion criteria for patients' relatives: being one of the health care workers.

Intervention groups
In intervention group educational sessions will be held for participants regarding to chemotherapy complication control. Also the nutritional regimen will be determined for patients and consultation and guidance by phone will continue for patients and their families for three months during chemotherapy. If the participants need psychiatric counseling, an appointment with one of the psychiatrists of the hospital for intervention group will be coordinated. In control group Patients will receive the only routine intervention including staffs' oral explanation in the field of chemotherapy. This routine intervention will also be conducted in the hospital for intervention group.

Main outcome variables
24 chemotherapy complications including nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170803035479N3**
Registration date: **2019-03-01, 1397/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-01, 1397/12/10**
Update count: **0**

Registration date
2019-03-01, 1397/12/10

Registrant information

Name
Leila Sayadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of family-centered supportive program and routine care on chemotherapy complications among leukaemia patients

Public title
Family-centered supportive program and chemotherapy complications
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria for patients: Have age over 18 years old Being able to understand and speak Persian and have the ability to read and write Have awareness of time, place and person Consent to participate in the study Acute lymphatic leukemia have been diagnosed for them For chemotherapy, at least, one of the family members who take care of patient at home accompanies him/her Have been referred to chemotherapy clinic and have being under consolidation chemotherapy Be the first or second turn of consolidation chemotherapy for these people Family members Inclusion Criteria: Have age between 18 to 60 years old Ability to understand Persian language and speak Persian, have ability of reading and writing Being aware of time, place and person being one of the first degree relatives of patient, and providing patient care at home and willing to participate in the study The patient obeys the relative They are personnel of the health system
Exclusion criteria:
Patients exclusion criteria: Have history of Chemotherapy in family members being one of the health system personnel Family member exclusion criteria: being one of the health system personnel
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding of patients, their family and researcher in this study is not possible and only statistician will not be aware of the allocation of patients to control or intervention group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional research ethics committee of Nursing, Midwifery & Rehabilitation school
Street address
School of Nursing and Midwifery,Tehran University of Medical Sciences, Nosrat street. Tohid sq.
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2018-12-19, 1397/09/28
Ethics committee reference number
IR.TUMS.FNM.REC.1397.165

Health conditions studied

1

Description of health condition studied
Acute lymphoblastic leukaemia
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description
Nausea or vomiting before treatment
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

2

Description
Nausea after treatment
Timepoint
Before starting the first or second chemotherapy

sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

3

Description

Vomiting after treatment

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

the Chemotherapy Symptom Assessment Scale

4

Description

Constipation

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

the Chemotherapy Symptom Assessment Scale

5

Description

Diarrhea

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

6

Description

pain

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

7

Description

Shortness of breath

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

8

Description

Signs of infection

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

9

Description

Bleeding or bruising

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

10

Description

Needles/numbness of hands and feet

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

11

Description

Problems with the skin and nails

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

12

Description

Hair loss

Timepoint

Before starting the first or second chemotherapy, and then in each chemotherapy session until 3 months - number of chemotherapy depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

13

Description
A sore/sensitive mouth or throat
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

14

Description
A change in appetite
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

15

Description
Weight gain or loss
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

16

Description
Sore/scratchy/dry eyes
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

17

Description
Feeling weakness
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

18

Description
Feeling unusual fatigue
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

19

Description
Difficulty sleeping
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

20

Description
Headaches
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

21

Description
Feeling distressed/anxious
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

22

Description
Feeling pessimistic/unhappy
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol
Method of measurement
The Chemotherapy Symptom Assessment Scale

23

Description
Change in sexual life
Timepoint
Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3

months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

24

Description

Irregular periods (in female patients)

Timepoint

Before starting the first or second chemotherapy sessions, and then in each chemotherapy session until 3 months - number of chemotherapy sessions depend on the chemotherapy protocol

Method of measurement

The Chemotherapy Symptom Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention, performed in this study, is a family-based support program (Including family and patient education, determining the type of patient's diet, and psychological support). In order to patient and family member education, pamphlets/ information booklets and educational videos will be prepared. At the first meeting with patients and their family members before starting consolidated Chemotherapy (first stage or second stage), which will be held at the chemotherapy clinics, the training video provided for them will be displayed as well as video and pamphlet given to them. In the session oral explanations on the content of video and educational pamphlets will also be provided for families and patients, and the questions posed by them will be answered. This training session will be held for at least an hour. The number of patients and family members attending this session is based on the number of patients with acute lymphatic leukemia under chemotherapy on that day. After that according to the patient's condition a dietitian will be consulted in order to prepare a patient's diet. Prepared diet will be given to the family member after approval of doctor at the next session of chemotherapy. And guidelines on appropriate nutrition of these patients will be provided for the family. Afterwards, patients and their families will be followed up by phone. During the follow up period, the necessary supportive programs are used in accordance with the new drug or procedure and also controlling the side effects of chemotherapy in families and patients will be presented. Phone follow-up period will be continued for three months during chemotherapy for each patient and their families. Since, Consolidation chemotherapy is performed in these patients phone follow up will be done every two weeks (between two weeks and up to three months). If in the training sessions and in phone follow-up, need to psychological counseling on problems of patients after chemotherapy for patient and the family is confirmed, they will be referred to a psychiatrist at the Hematology Research Center

Category

Other

2

Description

Control group: Patients in control group, will be received the only routine intervention of chemotherapy clinics that include oral explanations of staff in the field of chemotherapy. This routine intervention is also being conducted at the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital,Tehran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Mehrpoor

Street address

Shariati hospital, Jalal Ahmad Street, Kargar street

City

Tehran

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1411713135

Phone

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Email

shariatihosp@tums.ac.ir

Web page address

http://shariati.tums.ac.ir/cpages/mainpage.asp?l=S1M5P2C1

2

Recruitment center

Name of recruitment center

Taleqani Hospital

Full name of responsible person

Dr. Reza Zandi

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Velenjak St. , Shahid Chamran Highway

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Province

Tehran

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Fax

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Email

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Web page address

https://taleghani.sbmu.ac.ir/index.jsp?fkeyid=&siteid=88&pageid=2954

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohamad Ali Sahraeiyan

Street address

Deputy of Research and Technology, Sixth Floor, Central Organization of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

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Tehran

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Tehran

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Email

nmcrc@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Tehran University of Medical Sciences

Full name of responsible person

Melika Babazadeh Zanjani

Position

MS Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Leila Sayadi

Position

Assisstant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Leila Sayadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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City

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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