Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of palliative care program on the quality of life of children with leukemia

Protocol summary

Study aim
The effect of pediatric care program on the quality of life of children with leukemia

Design
En Design of study: Non randomized , with parallel group, not blind, with group controlled; Society studied is 60 children with leukemia under chemotherapy Hospitalization in the Doctor Sheikh hospital of Mashhad.

Settings and conduct
The research is conducted at Sheikh Hospital in Mashhad. In the allocation process, the children will be randomly selected within the age range of the type of leukemia as well as the time of diagnosis of the disease, and will be placed in two groups of "reliever care" and "control"; first, patients entered the control group and then the palliative care group With the same proportion, they will be included in the study. Intervention involves three stages of treatment for leukemia: 1-induction-2-booster therapy 3- preservative therapy. Palliative care decisions are made with the participation of the child and his family and the health team including physicians, nurses, social workers, psychologists and clerics. Two weeks prior to the intervention, the researcher provides the members with educational chapters, and holds two briefing sessions before the intervention, and at the end of each week, the researcher will hold a meeting with all members of the palliative care team and Interventions will be reviewed. The intervention period is 4 weeks.

Participants/Inclusion and exclusion criteria
En Inclusion criteria: Children aged 12-6 years with leukemia, not being in the final stages of life, age range. Exclusion criteria: The patient's reluctance to continue participating in this study.

Intervention groups
Palliative care will be performed for the intervention group for 4 weeks. The control group does not receive any other intervention.

Main outcome variables
Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180531039925N1**
Registration date: **2018-08-28, 1397/06/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-28, 1397/06/06**
Update count: **0**

Registration date
2018-08-28, 1397/06/06

Registrant information

Name
Raziyeh Saravani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3851 6300

Email address
saravanir951@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-05, 1397/03/15

Expected recruitment end date
2018-11-06, 1397/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of palliative care program on the quality of life of children with leukemia

Public title
The effect of palliative care on leukemia quality of life
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
En children aged 6-12 years with leukemia Not being in the final stages of life
Exclusion criteria:
En Patient’s unwillingness to continue the collaboration in this study
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Mashhad university of medical siences
Street address
Ghoreishi building.daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2018-05-05, 1397/02/15
Ethics committee reference number
IR.MUMS.REC.1397.040

Health conditions studied

1

Description of health condition studied
Leukemia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life
Timepoint
En At beginning the study and one month later
Method of measurement
Ped QL Cancer Modules

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, palliative care will be performed for 4 weeks
Category
Treatment - Other

2

Description
Control group: no intervention
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Doctor Sheikh hospita
Full name of responsible person
Dr Zahra Badee
Street address
Doctor Sheikh Hospital, Tohid Square, Motahari Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
917351358
Phone
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Fax

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Email
Shaikh.hospital@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Ghoreishi building. Daneshgah street
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vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
دانشگاه علوم پزشکی مشهد
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
Mashhad University of Medical Sciences
Full name of responsible person
Raziyeh Saravani
Position
Nursing Master
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Position
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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
Not applicable