

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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 sciences

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

+98 51 3726 9021

Fax

+98 51 3726 9021

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

Street address

school of Nursing & Midwifery, Ibn sina avenue

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Razavi Khorasan

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9137913199

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Email

Saravanir951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamidreza Behnam Vashani

Position

Master of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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Email

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