Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of food safety guidelines in comparison to the neutropenic diet on infection rates in patients with acute myeloid leukemia undergoing remission induction chemotherapy: a randomized clinical trial

Protocol summary

Study aim

determine The effects of food safety guidelines in comparison to the neutropenic diet on infection rates in patients with acute myeloid leukemia undergoing remission induction chemotherapy

Design

In this randomized clinical trial, Phase 2 will be taken from 68 patients using a general information questionnaire. Anthropometric measurements will be taken before the intervention begins. Three 24-hour food records will be taken from patients at the beginning, middle and end of the study, and their quality of life scores will be assessed using the EORTC QLQ-C30 questionnaire before the intervention and at the end of the intervention. To better follow the intervention, people will be consulted face to face twice a week

Settings and conduct

This study will be performed as a clinical trial on patients with acute myeloid leukemia under induction chemotherapy. Participants will be selected from patients admitted to Shariati Hospital in Tehran in 1400 based on the inclusion criteria.

Participants/Inclusion and exclusion criteria

Adults with AML undergoing induction chemotherapy, aged 20-55 years, will be enrolled in the absence of active infection at the time of admission and with a Karnofsky Performance Scale Index of more than 70%, and individuals with chronic obstructive pulmonary disease will fail. Chronic kidney, diabetes and asthma will not be included in the study.

Intervention groups

The neutropenic diet group uses neutropenic guidelines for 4 weeks. Participants in the Food Safety guidelines Group will receive detailed information, including how to buy, prepare, store, cook, and how to serve and consume food safely, for 4 weeks

Main outcome variables

Early onset of fever and neutropenia; Quality of Life ; Incidence of bacteremia; Incidence of pneumonia; Incidence of fungal infections; Duration of use of antibiotics or antifungals; Incidence of infectious diarrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220208053971N1**
Registration date: **2022-04-16, 1401/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-16, 1401/01/27**
Update count: **0**

Registration date

2022-04-16, 1401/01/27

Registrant information

Name

Hamed Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

hmohamadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-02, 1401/01/13

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of food safety guidelines in comparison to the neutropenic diet on infection rates in patients with acute myeloid leukemia undergoing remission induction chemotherapy: a randomized clinical trial

Public title

The effects of food safety guidelines in comparison to the neutropenic diet on infection rates in patients with acute myeloid leukemia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of acute myeloid leukemia Admission to the ward to start induction chemotherapy Willingness to cooperate

Exclusion criteria:

Infection or febrile illness at the time of admission Karnofsky Performance Status Scale less than 70% Chronic obstructive pulmonary disease, chronic renal failure, diabetes and asthma

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization method is used for randomization. In this method, eligible individuals with inclusion criteria are selected and then they are randomly selected using blocks with the size of 4 subjects, that blocks will be based on age (20 to 40 and 40 to 55 years) and gender (female / male). Then all possible sequences that can be written with block size of 4, were written on paper (for two groups with block size of 4, 6 sequences can be written). Then one of the numbers from 1 to 6 was considered for each sequence, for example for the ABBA sequence 1 and for the AABB sequence 2 and as such, one of the numbers 3 to 6 was considered for the other 4 sequences. Then, using random number table, the random numbers were selected from one point to the left or right. Wherever the random number was 1 to 6, the corresponding sequence was recorded on the paper, and wherever the numbers were 0 or 7, 8, 9, the next number that was between 1 to 6 was considered. This method continued until groups for the total number of participants were determined. Then, the names of subjects on the list were allocated to the specific groups according to the sequence of groups which had been determined by the above-mentioned procedure.

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 Tehran University of Medical sciences

Street address

Room 605, Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

141556117

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1391

Health conditions studied

1

Description of health condition studied

Acute myeloid leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes

1

Description

The first episode of fever

Timepoint

From the first day of intervention for 4 weeks

Method of measurement

Temperatures above 38.3 degrees at one time or above 38 at two times with an interval of one hour

2

Description
Incidence of bacteremia
Timepoint
From the first day of intervention for 4 weeks
Method of measurement
Patient file

3

Description
Incidence of pneumonia
Timepoint
From the first day of intervention for 4 weeks
Method of measurement
Patient file

4

Description
Incidence of fungal infections
Timepoint
From the first day of intervention for 4 weeks
Method of measurement
Patient file

5

Description
Duration of use of antibiotics or antifungals
Timepoint
From the first day of intervention for 4 weeks
Method of measurement
Patient file

6

Description
Infectious diarrhea
Timepoint
From the first day of intervention for 4 weeks
Method of measurement
Patient file

7

Description
Type of documented organisms
Timepoint
From the first day of intervention for 4 weeks
Method of measurement
Patient file

8

Description
Average length of hospital stay
Timepoint
From the first day of intervention for 4 weeks
Method of measurement
Patient file

9

Description
Quality of Life
Timepoint
Beginning and end of the study
Method of measurement
EORTC QLQ-C30 Questionnaire

10

Description
Number of infections per 1000 patient-day
Timepoint
From the first day of intervention for 4 weeks
Method of measurement
Patient file

11

Description
Nutritional status
Timepoint
Beginning and end of the study
Method of measurement
PG-SGA questionnaire

12

Description
Following the prescribed regimen
Timepoint
First, middle and end of the study
Method of measurement
Three 24-hour food records

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group of food safety guidelines will receive detailed information including how to buy, prepare, store, cook and how to serve and consume food safely and will follow this guidelines for 4 weeks. In order to assess the adherence of patients' diets during the intervention, three 24-hour 3-day food records will be taken from patients at the beginning, middle and end of the intervention. Quality of life scores will be assessed using the EORTC QLQ-C30 questionnaire before the intervention and at the end of the intervention. In order for people to better follow the intervention, face-to-face counseling will be done twice a week, and possible problems related to diet adherence will be examined and the necessary instructions will be provided.
Category
Prevention

2

Description
Intervention group: The neutropenic diet group uses standard neutropenic guidelines that generally include the elimination of raw fruits and vegetables, soft cheeses, probiotic yogurt, undercooked meat and eggs, and tap water, spices, and alcoholic beverages. They will follow this diet for 4 weeks. In order to assess the adherence of patients' diets during the intervention, three 24-hour 3-day food records will be taken from patients at the beginning, middle and end of the intervention. Quality of life scores will be assessed using the EORTC QLQ-C30 questionnaire before the intervention and at the end of the intervention. In order for people to better follow the intervention, face-to-face counseling will be done twice a week, and possible problems related to diet adherence will be examined and the necessary instructions will be provided.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati hospital

Full name of responsible person
Dr. Hamed Mohammadi

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Kargar Shomali Street, Jalal-e-Al-e-Ahmad hwy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran university of medical science

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
Dr. Hamed Mohammadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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
Due to confidentiality of participant information, it is not possible to publish it
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not 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
Not applicable
Data Dictionary
Not applicable