

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

+98 21 8822 1444

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 AAB 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

Street address

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

City

Tehran

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1411713135

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shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotoohi

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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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No. 44, Shahid Hojjat Doost Alley, Naderi St, Keshavarz Boulevard

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Person responsible for scientific 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

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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student

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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