

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Peppermint (*Mentha piperita*) on Nausea, Vomiting and Anorexia in pediatrics with leukemia Undergoing Chemotherapy: A Randomized Controlled Trial

Protocol summary

Study aim

The effect of mint on nausea, vomiting and anorexia in children with leukemia

Design

Study is a randomized clinical trial that will be performed on two groups of patients (control and intervention). Phase 3 is study that will be performed on 68 patients. Rand function in Excel software will also be used.

Settings and conduct

The study is a randomized clinical trial in quadruple blocks in which the collector and statistical expert are not aware of how to blind the samples.

Participants/Inclusion and exclusion criteria

Inclusion criteria: written consent to participate in the study, definitive diagnosis of myeloid leukemia and acute lymphocytic (other than None M3ALL), receiving chemotherapy, history) Receive at least one course of chemotherapy, history of nausea experience following previous chemotherapy sessions ,, Age 3 to 18 years No entry conditions :nausea and vomiting resistant to treatment, severe gastrointestinal problems, other nausea problems such as hypertension, liver failure, kidney, concomitant radiotherapy with chemotherapy, allergy to mint

Intervention groups

The number of vomits in the day before chemotherapy in the intervention group and the control group are examined. In the intervention group, in addition to routine anti-nausea treatments, 12 hours before chemotherapy and up to 48 hours after, 1 drop in weight every 8 hours, peppermint extract (Super Mate drops) with 20 cc Urban tap water is given to patients The control group, they receive only routine anti-nausea drugs.

Main outcome variables

Nausea, vomiting, anorexia, leukemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037733N4**

Registration date: **2021-12-15, 1400/09/24**

Registration timing: **prospective**

Last update: **2021-12-15, 1400/09/24**

Update count: **0**

Registration date

2021-12-15, 1400/09/24

Registrant information

Name

Mehran Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-21, 1400/09/30

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Peppermint (Mentha piperita) on Nausea, Vomiting and Anorexia in pediatrics with leukemia Undergoing Chemotherapy: A Randomized Controlled Trial

Public title

Effect of pippermint on nausea in pediatrics with leukemia undergoing chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written consent to participate in the study
Definitive diagnosis of myeloid leukemia and acute lymphocytic (ALL and AML) by a pediatric hematologist and oncologist (other than None M3ALL)
Receiving chemotherapy courses
History of receiving at least one course of chemotherapy
Experience of nausea following previous chemotherapy sessions
No concomitant radiotherapy with chemotherapy
Age 3 to 18 years

Exclusion criteria:

Using medications or other treatments to reduce nausea other than the usual prescribed anti-nausea and vomiting medications (especially herbal remedies)
Nausea and vomiting resistant to treatment
Unwillingness to participating in the study
sensitivity to mint
other nausea problems such as hypertension , liver failure , kidney and digestive problems

Age

From **3 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are available from among children with acute myeloid leukemia and lymphocytosis undergoing chemotherapy. The samples are then assigned to two random groups as random quadruple blocks A, A, B, and B. It should be noted that the Rand function in Excel software will be used for randomization. The statistician and the sample collector are not aware of how the samples are blinded.

Blinding (investigator's opinion)

Double blinded

Blinding description

The statistician will do the randomization, one of the colleagues will do the sampling plan, and the treating physician will assign the patients to the groups. The statistician and the sample collector are not aware of how the samples are blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Payambar aazam, University Complex, Basij SQ, Sardasht region

City

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Markazi

Postal code

6941-7-38481

Approval date

2021-11-08, 1400/08/17

Ethics committee reference number

IR.ARAKMU.REC.1400.211

Health conditions studied

1

Description of health condition studied

Nausea, vomiting and Anorexia

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea

Timepoint

Before, immediately, 24 hours, 48 hours after chemotherapy

Method of measurement

VAS questionnaire and measurement table and Face scale

2

Description

Vomiting

Timepoint

Before, immediately, 24 hours, 48 hours after chemotherapy

Method of measurement

VAS questionnaire and measurement table and Face scale

3

Description

Anorexia

Timepoint

Before, immediately, 24 hours, 48 hours after chemotherapy

Method of measurement

VAS questionnaire and measurement table and Face scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The samples are assigned to two random groups as quadruple random blocks A, A, B, and B. First, written and informed consent was obtained from the patients. Then, with the help of VAS visual scale, the amount of nausea and anorexia and with the help of frequency table, the number of vomiting cases in the day before chemotherapy in the intervention and control groups are examined. In the intervention group, in addition to routine anti-nausea treatments, 12 hours before chemotherapy and up to 48 hours after, 1 drop in weight (1 Drop per kilogram) every 8 hours, peppermint extract (Super Mate drops) (Barij Essence Pharmaceutical Company) with 20 cc Urban tap water is given to patients (measurement of nausea, vomiting and anorexia half an hour before chemotherapy, immediately, 24 and 48 hours after chemotherapy). All medications taken are recorded by the sample collector.

Category

Treatment - Drugs

2

Description

Control group: In the control group, they receive only routine anti-nausea drugs and their nausea, vomiting and anorexia are measured by VAS scale half an hour before chemotherapy, immediately, 24 and 48 hours after re-chemotherapy.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ward of Pediatric Blood and Oncology, Amirkabir Hospital of Arak city,

Full name of responsible person

Mehran Akbari

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Railway Street, Amir Kabir Educational and Medical Center, Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

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?

Yes

Title of funding source

Arak 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

Khomein University of Medical Sciences

Full name of responsible person

Mehran Akbari

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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