

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of oral care program and honey mouthwash on mucositis, weight loss and quality of life of patients with Acute Myeloid leukemia undergoing chemotherapy: A Randomized Clinical Trial

Protocol summary

Summary

This study aimed to determine the effect of oral care protocol, honey mouthwash and compare the effects of two types of intervention on prevention of mucositis, weight loss and quality of life of patients with acute myeloid leukemia under Chemotherapy at Ghazi Tabatabaie hospital in Tabriz .This study is a Single-blind randomized clinical trial for four weeks in the three groups (oral care, honey mouthwash and control) will be done. Finally, 51 patients (17 patients per group) of male and female patients that having Inclusion criteria; adults (over 18 years) with acute myeloid leukemia undergoing chemotherapy for the first time under chemotherapy (7 + 3 regimen) and exclusion criteria: thrombocytopenia and promyelocytic leukemia will be randomly selected. In oral care group, participants will use soft toothbrush twice a day, flossing once a day and normal saline oral rinse three times a day before and after every eating meal and before bed-time. Honey mouthwash group, a solution of a tablespoon of honey in a glass of mild water and gargle three times a day, before and after each meal and before bed time. The control group will receive routine care. The main outcome of the study is mucositis. . For measuring Weight and mucositis outcomes, instruments will be completed once before and then at the end of each week and quality of life instrument will be completed once before and once at the end of four weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121419919N7**

Registration date: **2016-02-01, 1394/11/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-01, 1394/11/12

Registrant information

Name

Arefeh Davoodi Babil Oliai

Name of organization / entity

Nursing and Midwifery of Faculty, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-12-31, 1394/10/10

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral care program and honey mouthwash on mucositis, weight loss and quality of life of patients with Acute Myeloid leukemia undergoing chemotherapy: A Randomized Clinical Trial

Public title

The effect of oral care and honey mouthwash on the mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Adults (over 18 years) undergoing chemotherapy with AML is the first candidate for chemotherapy. Not using smoking, hookah, tobacco, opioid and alcohol, do not receive radiotherapy and treated with induction (3+7 regimen) Exclusion criteria: discharged against medical advice or death during study, lack of patient cooperation, having thrombocytopenia (platelet count less than 20,000 per m m3), previous radiotherapy and chemotherapy in patients, promyelocytic leukemia AML m3 for treatment of arsenic (if the patient along with arsenic regimen 3+7 receive will be part of the intervention group)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Tabriz University of Medical Sciences

Street address

South Shariety St; Faculty of Nursing and Midwifery-Tabriz, East Azarbayjan Iran, Islamic Republic Of

City

Tabriz

Postal code

51745347

Approval date

2016-01-06, 1394/10/16

Ethics committee reference number

11458/4/5

Health conditions studied**1****Description of health condition studied**

mucositis

ICD-10 code

K12.3

ICD-10 code description

(Oral mucositis (ulcerative

Primary outcomes**1****Description**

mucositis

Timepoint

Once before and four after the intervention (at the end of the first week, second, third and fourth)

Method of measurement

WHO scale

Secondary outcomes**1****Description**

Quality of life

Timepoint

Once before and once at the end of the fourth week after intervention

Method of measurement

EORTC QLQ - C30 . V .3 questionnaire

2**Description**

weight

Timepoint

Once before and four after the intervention (at the end of the first week, second, third and fourth)

Method of measurement

Balance

Intervention groups**1****Description**

In oral care intervention program involves the use of a soft toothbrush twice a day, flossing once, three times a day before and after every meal and before bed-time of normal saline (60 mL for 30 seconds) will be used. Finally, a written training program will be given to the patient and his family Water will be used to protect the lips

Category

Prevention

2

Description

The intervention group that receive honey mouthwash, a solution of a big tablespoon of honey that will be solved in mild water gurgled and keep in the mouth that can involve the entire surface of the mouth, gums and tongue. this solution, will be three times a day, before and after eating meal and once before sleeping, for 30 seconds.

Category

Prevention

3

Description

In the control group patients only receive routine care and intervention will be done.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghazi tabatabaie hospital in the Tabriz

Full name of responsible person

Arezoo khanjani

Street address

Shariety South St ; Faculty of Nursing and Midwifery

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Kazem Shakori

Street address

Deputy of Medical Sciences University of Tabriz, Tabriz, Est Azarbayjan

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Arezoo khanjani

Position

Nursing student of MS/ Nurse

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty