Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Randomaized 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 gurgle 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 Bavil Oliaii

Name of organization / entity
Nursing and Midwifery of Faculty, Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 3477 0648

Email address
adavoodi@tbzmed.ac.ir

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 Randomaized 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

Other areas of specialty/work

Street address
South Shariety St; Faculty of Nursing and Midwifery

City
Tabriz

Postal code

Phone
+98 41 3347 7379

Fax

Email
arezookhanjani68@ gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Azad Rahmani

Position
Master of nursing

Other areas of specialty/work

Street address
South Shariety St; Faculty of Nursing and Midwifery

City
Tabriz

Postal code

Phone
+98 41 3347 7379

Fax

Email
azad.rahmani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Azadeh Rahmani

Position
Master of nursing- Faculty member

Other areas of specialty/work
Street address
Shariety South St ; Faculty of Nursing and Midwifery
City
Tabriz
Postal code
Phone
+98 41 3347 7379
Fax
Email
azad.rahmani@yahoo.com
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