

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of Aloe vera mouthwashe on the intensity of stomatitis and related pain in all patients with leukemia and lymphoma who receiving chemotherapy refferd to hospitals affiliated to Shiraz University of Medical Science.

Protocol summary

Summary

Study objective: The main objective of the project: The effect of Aloe vera mouthwashe on the intensity of stomatitis and related pain in patients with leukemia and lymphoma who receiving chemotherapy refferd to hospitals affiliated to Shiraz University of Medical Science- Design of study: randomized, single blind, controlled- study population: All patients with lymphoma and leukemia refferd to the hospitals affiliated to Shiraz University of Medical Science. main inclusion criteria: Willingness to participate in the study; Minimum age of 18 years; New diagnosed cancer with AML and ALL; Absence of underlying disease; No addiction to cigar, tobacco; The lack of context sensitivity on aloe vera. Main exclusion criteria: food allergy to the substances during the study; A critical condition during the study that causes patients exclusion. sample size: 64 people- study Intervention: patients will be divided into two groups based on the list of random numbers. in the intervention group patients will use 5cc aloe vera 3 times daily. controls patients will use only prescribed mouthwashes. To investigate the effects of drugs on the degree of mucositis, the table provided by the World Health Organization (WHO) will be used. Expected recruitment start date: 23/8/2014- Expected recruitment end date: 23/10/2014- Study primary outcome: stomatitis grade and related pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092819318N1**
Registration date: **2014-11-02, 1393/08/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-02, 1393/08/11

Registrant information

Name

Maryam Haghighi

Name of organization / entity

Shiraz University of Medical Science and Health Services

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Iran (Islamic Republic of)

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+98 32297527

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science and Health Services

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Aloe vera mouthwashe on the intensity of stomatitis and related pain in all patients with leukemia and lymphoma who receiving chemotherapy refferd to hospitals affiliated to Shiraz University of Medical

Science.

Public title

Effect of aloe vera on chemotherapy induced stomatitis

Purpose

Supportive

Inclusion/Exclusion criteria

Main inclusion criteria: Willingness to participate in the study; Minimum age of 18 years; New diagnosed cancer with AML and ALL; Absence of underlying disease; No addiction to cigar,tobacco; The lack of context sensitivity on aloe vera. Main exclusion criteria: food allergy to the substances during the study; A cirritical condition during the study that causes patients exclusion.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

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

shiraz university of medical science and health services

Street address

shiraz, zand blv, central building of shiraz university of medical science

City

shiraz

Postal code

71345-1978

Approval date

2014-08-04, 1393/05/13

Ethics committee reference number

CT-9374-7114

Health conditions studied

1

Description of health condition studied

AML

ICD-10 code

c92

ICD-10 code description

Acute Myeloblastic Leukaemia

2

Description of health condition studied

ALL

ICD-10 code

C91

ICD-10 code description

Acute Lymphoblastic Leukaemia

Primary outcomes

1

Description

intensity of stomatitis

Timepoint

5 visit in 2 weeks, in 1th, 3th,5th,7th,14th days

Method of measurement

stomatitis scale provided by WHO

2

Description

stomatitis related pain

Timepoint

2 weeks, 5 visit in 1th,3th,5th,7th,14th days

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

interventional group: prescription of aloe vera mouthwashe. for 2 weeks and 3 time daily, using 5 cc of aloevera mouthwashe each time.

Category

Treatment - Drugs

2

Description

patient will used commonly prescribed mouthwashes in hemathology and oncology departments for 2 weeks and 3 times/ day 5 cc each times.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Dr Mani Ramzi, Oncologist

Street address

Namazi Hospital, Namazi square, shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Shaheed Motahari Clinic

Full name of responsible person

Dr Mani Ramzi, Oncologist

Street address

Fourth floor, Shaheed Motahari Clinic, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Science and Health Services

Full name of responsible person

Dr Seyed Basir Hashemi

Street address

Research Deputy, Central building of Shiraz University of Medical Science, Blv Zand

City

Shiraz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Science and Health Services

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

School of Nursing-Midwifery Fatemem

Full name of responsible person

MA Parisa Mansoori

Position

Master of Nursing/ Nursing Mentor

Other areas of specialty/work
Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Dr Mani Ramzi

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Oncologist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Maryam Haghighi

Position

Master of nursing student

Other areas of specialty/work
Street address

Shahab building, Khakshenasi 9

City

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Phone

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Fax

Email

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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