

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

**The effect of Aloe vera mouthwashes on the intensity of stomatitis and related pain in all patients with leukemia and lymphoma who receiving chemotherapy referred 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 mouthwashes on the intensity of stomatitis and related pain in patients with leukemia and lymphoma who receiving chemotherapy referred to hospitals affiliated to Shiraz University of Medical Science- Design of study: randomized, single blind, controlled- study population: All patients with lymphoma and leukemia referred 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 Haghghi

##### Name of organization / entity

Shiraz University of Medical Science and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 32297527

##### Email address

haghghi\_ma@sums.ac.ir

#### 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 mouthwashes on the intensity of stomatitis and related pain in all patients with leukemia and lymphoma who receiving chemotherapy referred 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**

School of Nursing-Midwifery Fatemem, Namazi Square.

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Science

**Full name of responsible person**

Dr Mani Ramzi

**Position**

Oncologist

**Other areas of specialty/work**

**Street address**

Department of bone marrow transplantation, Namazi hospital

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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

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**Fax**

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hgh\_maryam@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*