Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trials the effect of aqueous extract of salvia officinalis for Preventing Stomatitis in Children With leukemia Undergoing Chemotherapy

Protocol summary

Summary

Objective:This single-blind clinical trial of the experimental and control groups with the aim of determine the effect of aqueous extract of sage on Preventing Stomatitis in children with Leukemia that admitted to the Hospital Besat Hematology Chemotherapy Unit in 1396. In this study, 54 patients with Cancer receiving chemotherapy were enrolled and randomly method available in any of the treatment groups (Rinse with water extract of sage) and control (Normal saline Mouthwash) are placed. In the control group patients only recived routine treatment for patients with Stomatitis and in the experimental group used the routine treatment for mouth rinse in addition to 3 drops of extract in 2 ml water, diluted, enter the patient's mouth after brushing their teeth and mouth are rotated in and out for 1 minute and until 1hour did not eat anything. To measure the effects of saline and aqueous extracts of sage on the severity of stomatitis use of the World Health Organization standard tools.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011732025N1**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Arash Khalili

Name of organization / entity

Hamadan University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials the effect of aqueous extract of salvia officinalis for Preventing Stomatitis in Children With leukemia Undergoing Chemotherapy

Public title

The effect of aqueous extract of salvia officinalis for Preventing Stomatitis in Children With leukemia Undergoing Chemotherapy In Besat hospital.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:The age of 6 to 14 years; Children's be admitted in Hematology Hospital Besat; children is leukemia; child or caregiver and are now teaching the

Persian language; baby have at least once chemotherapy and for the prevention of stomatitis to be hospitalized by doctor; Lack of sensitivity to drug sage Exclusion criteria: lack of desire to continue to participate in the study; out of the study for any reason during the study, such as death, relocation and ....

Age
From **5 years** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan University Of Medical Scinces

Street address
Hamadan University Of Medical Scinces, Shahid Fahmideh Boulvard, Hamadan, Iran.

City
Hamadan

Postal code

Approval date
2017-01-14, 1395/10/25

Ethics committee reference number
IR.UMSHA.REC.1395.450

Health conditions studied

1

Description of health condition studied
ALL

ICD-10 code
C91.0

ICD-10 code description
Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description
Stomatitis

Timepoint
1week

Method of measurement
Oral Mucositis Assessment Scale

Secondary outcomes

1

Description
Oral Wound

Timepoint
1 Week

Method of measurement
Oral Mucositis Assessment Scale

Intervention groups

1

Description
This randomized, double-blind study, with a test group and a control group hematology hospital in Besat enforced. 60 leukemia patients undergoing chemotherapy simple random way in each of the treatment groups (rinse with water extract of sage and cocktails solution of 30 patients) and control (rinse with a solution of cocktails, 30) are placed. in the experimental group used the routine treatment for mouth rinse in addition to 3 drops of extract in 2 ml water, diluted, enter the patient's mouth after brushing their teeth and mouth are rotated in and out for 1 minute and until 1hour did not eat anything.

Category
Prevention

2

Description
In the control group patients only recived routine treatment for patients with Stomatitis

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hamadan Hospital

Full name of responsible person
Fariba Ebrahimi

Street address
Hamadan, Besat Hamadan Hospital

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Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University Of Medical Scinces
Full name of responsible person
Fariba Ebrahimi Horyat
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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
Hamadan University Of Medical Scinces
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

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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