

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Study of the effect of chamomile syrup oral application in prevention of chemotherapy-induced neutropenia in pediatric ALL patients

Protocol summary

Summary

In this study, effect of chamomile syrup on prevention of chemotherapy induced neutropenia in pediatric ALL patients will be investigated through a randomized triple blind placebo controlled clinical trial. Main inclusion criterion is 2-18 years old children with ALL B cell admitted in hospital, while those with sensitivity to chamomile will be excluded. A total number 36 participants in each group will receive 2.5 cc of either chamomile syrup or placebo once daily for 30 days. Their white blood cell count, absolute neutrophil count, and quality of life will be measured before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021612486N1**
Registration date: **2017-05-30, 1396/03/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-30, 1396/03/09

Registrant information

Name

Babak Daneshfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 8867

Email address

daneshfard@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of chamomile syrup oral application in prevention of chemotherapy-induced neutropenia in pediatric ALL patients

Public title

Effect of chamomile syrup on acute leukemia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Pediatric (2-18 years old) ALL B cell patients admitted in Shiraz Amir hospital ; Signing written informed consent; Non-usage of any other herbal therapies. Exclusion Criteria: Sensitivity to chamomile; Refuse to cooperate

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Zand
City
Shiraz
Postal code
7134845794
Approval date
2017-04-17, 1396/01/28
Ethics committee reference number
IR.SUMS.REC.1396.11

Health conditions studied

1

Description of health condition studied
Acute Lymphoblastic Leukemia (ALL)
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description
GCSF consumption
Timepoint
before and after the intervention
Method of measurement
Checking hospital documents

2

Description
Absolute Neutrophil Count (ANC)
Timepoint
before, during, and after the intervention
Method of measurement

Calculation according to the white blood cell count and neutrophil percentage

Secondary outcomes

1

Description
Quality of life
Timepoint
before and after the intervention
Method of measurement
Standard questionnaire

2

Description
Hospital course duration
Timepoint
after the intervention
Method of measurement
Hospital documents

Intervention groups

1

Description
Daily 2.5 cc chamomile syrup orally for 30 days in the intervention group
Category
Prevention

2

Description
Daily 2.5 cc placebo syrup orally for 30 days in the control group
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Oncology Hospital
Full name of responsible person
Babak Daneshfard
Street address
7th Floor- Building No 2-Medical School-Setad Sq.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shiraz University of Medical Sciences
Full name of responsible person
Deputy of Research
Street address
7th Floor-Central Building of University-Zand street
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 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
Shiraz University of Medical Sciences
Full name of responsible person
Babak Daneshfard
Position
MD, PhDc in Traditional Persian Medicine
Other areas of specialty/work
Street address
7th Floor- Building No 2-Medical School-Setad Sq.
City
Shiraz
Postal code
7134845794
Phone
+98 71 3234 5145
Fax
+98 71 3234 5145
Email
babakdaneshfard@gmail.comdaneshfard@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

Babak Daneshfard
Position
MD, PhDc in Traditional Persian Medicine
Other areas of specialty/work
Street address
7th Floor- Building No 2-Medical School-Setad Sq.
City
Shiraz
Postal code
7134845794
Phone
+98 71 3234 5145
Fax
+98 71 3234 5145
Email
babakdaneshfard@gmail.comdaneshfard@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Babak Daneshfard
Position
MD, PhDc in Traditional Persian Medicine
Other areas of specialty/work
Street address
7th Floor- Building No 2-Medical School-Setad Sq.
City
Shiraz
Postal code
7134845794
Phone
+98 71 3234 5145
Fax
+98 71 3234 5145
Email
babakdaneshfard@gmail.comdaneshfard@sums.ac.ir
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