

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effect of topical Sesame Oil in the Prevention of Chemotherapy-Induced Phlebitis in 17 Shahrivar Hospital

Protocol summary

Summary

Purpose: This study will be conducted to determine the effect of external use of Sesame oil (SO) in prevention of chemotherapy-induced phlebitis. Materials & Methods: 60 patients with Acute Lymphocytic Leukemia(ALL), who admitted for chemotherapeutic management, will be enrolled in a clinical trial and they will be randomly divided in two equal, control & intervention, groups. They will use 10 drops of SO every 12 hours, two times a day, from the first day of chemotherapy up to the thirtieth day. In control group liquid paraffin as placebo. The amount and method of using liquid paraffin is as exactly same as using of sesame oil in the experimental group. Data tools included a bipartite questionnaire (demographic Q & clinical Q) and Visual infusion phlebitis Scale (VIP) for measurement of phlebitis in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101924594N1**

Registration date: **2015-11-12, 1394/08/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-12, 1394/08/21

Registrant information

Name

Seyedeh Zahra Shafipour

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3344 0202

Email address

shafipur@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-11-11, 1394/08/20

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical Sesame Oil in the Prevention of Chemotherapy-Induced Phlebitis in 17 Shahrivar Hospital

Public title

Evaluation of the effect of topical Sesame Oil in the Prevention of Chemotherapy-Induced Phlebitis in 17 Shahrivar Hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: consciousness; age 1-14 years; admitted to hospital with ALL; chemotherapeutic management with Adriamycin & vincristine; Application No. 22-24 catheter mediflon Company; catheterization into arm vein; No septic conditions during catheterization; Underlying Co-morbidity (diabetes, infections, and hypertension); underlying fever and neutropenia; any broad spectrum antibiotic & narcotic analgesic in the patient medication instructions no received antibiotic & narcotic analgesic; received

another Vegetable oil or drug; history of Sesame family allergy. Exclusion criteria: Vessel rupture due to nursing error; Lack of chemotherapy drugs under the skin and surrounding tissues.

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Guilan University of Medical Sciences, in front of Sepah Bank, West Beheshti blvd., Rasht

City

Rasht

Postal code

4193893345

Approval date

2015-10-06, 1394/07/14

Ethics committee reference number

285

Health conditions studied

1

Description of health condition studied

phlebitis

ICD-10 code

T80.1

ICD-10 code description

Vascular complications following infusion, transfusion and therapeutic injection

Primary outcomes

1

Description

Phlebitis

Timepoint

Daily

Method of measurement

visual infusion phlebitis scale

Secondary outcomes

1

Description

Pain, Erythema, Swelling

Timepoint

Daily

Method of measurement

visual infusion phlebitis scale

Intervention groups

1

Description

Intervention 1: 10 drops of Sesame oil for external using, every 12 hours, two times a day, from the first day of chemotherapy up to the thirtieth day.

Category

Prevention

2

Description

In control group paraffin as placebo. The amount and method of using liquid paraffin is as exactly same as using of sesame oil in the experimental group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

Seyedeh Zahra Shafipour

Street address

Nursing and midwifery school, Daneshjo st., Beheshti Highway, Rasht.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

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Research and Technology affairs building, in front of
Sepah Bank, West Beheshti blvd., Rasht

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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

Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

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Position

Faculty member

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Person responsible for updating data

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Full name of responsible person

Nadia Mosayebi

Position

Ms

Other areas of specialty/work**Street address**

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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