

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of external use of Sesame oil in the prevention of chemotherapy-induced phlebitis

Protocol summary

Summary

Purpose: This study has been conducted to determine the effect of external use of Sesame oil (SO) in prevention of chemotherapy-induced phlebitis. Materials & Methods: 60 patients with colon & rectum cancer, who admitted for chemotherapeutic management, were enrolled in a clinical trial and they 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 fourteenth day. Data tools included a bipartite questionnaire (demographic Q & clinical Q) and Royal College of Nursing -Infusion Therapy scale (2010) for measurement of phlebitis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903082846N7**
Registration date: **2011-01-26, 1389/11/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-26, 1389/11/06

Registrant information

Name

Tahereh Ashktorab

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 1543

Email address

t_ashktorab@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2010-12-18, 1389/09/27

Expected recruitment end date

2011-02-09, 1389/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of external use of Sesame oil in the prevention of chemotherapy-induced phlebitis

Public title

Effect of external use of Sesame oil in the prevention of chemotherapy-induced phlebitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: consciousness/age 30-70 years/ admitted to hospital with colon or rectum cancer/ chemotherapeutic management with 5-fluorouracil / Application No. 20-18 catheter Supa Company/ catheterization into arm vein/ No septic conditions during catheterization. Exclusion criteria: 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.

Age

From **30 years** old to **70 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)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees1**Ethics committee****Name of ethics committee**

The International Branch of Shahid Beheshti
University of Medical Sciences

Street address

No.19, Shaheed Abbas Pour, Vali Asr

City

Tehran

Postal code

141553693

Approval date

2010-12-13, 1389/09/22

Ethics committee reference number

116/2910

Health conditions studied1**Description of health condition studied**

phlebitis

ICD-10 code

T80.1

ICD-10 code description

Vascular complications following infusion, transfusion
and therapeutic injection

Primary outcomes1**Description**

Phlebitis

Timepoint

Daily

Method of measurement

Observation with a check list

Secondary outcomes1**Description**

Pain, Erythema, Swelling

Timepoint

Daily

Method of measurement

Observation with a check list

Intervention groups1**Description**

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

Category

Prevention

2**Description**

Control: no intervention

Category

N/A

Recruitment centers1**Recruitment center****Name of recruitment center**

Emam Hosein Hospital

Full name of responsible person

Tahereh Ashktorab

Street address

Faculty of Nursing, Shahid Beheshti University of
Medical Sciences

City

Tehran

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Researcher

Full name of responsible person

Tahereh Ashktorab

Street address

Faculty of Nursing, Shahid Beheshti University of
Medical Sciences

City

Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Researcher
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
Faculty of Nursing, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Ashktorab
Position
PhD
Other areas of specialty/work
Street address
Valiasr Street, Highway Beginning Niayesh
City
Tehran
Postal code
Phone
+98 21 8865 5371
Fax
Email
t_ashktorab@sbmu.ac.irtashktorab@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of nursing , Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Ashktorab
Position

PhD
Other areas of specialty/work
Street address
Faculty of nursing , Shahid Beheshti University of Medical Sciences, valiasr street
City
Tehran
Postal code
Phone
+98 21 8865 5371
Fax
Email
t_ashktorab@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Faculty of nursing , Shahid Beheshti University of Medical Sciences,
Full name of responsible person
Niloufar Nekoozad
Position
Ms
Other areas of specialty/work
Street address
The International Branch of Shahid Beheshti University of Medical Sciences
City
Tehran
Postal code
Phone
Fax
Email
niloufarnekozad@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