

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the Effect of Nigella Sativa Oil in the Prevention of Chemotherapy- Induced Phlebitis

Protocol summary

Study aim

Examination of the Effect of Nigella Sativa Oil in the Prevention of Chemotherapy-Induced Phlebitis

Design

This clinical trial was conducted with a control group at Tohid Hospital in Sanandaj. 60 Patients with Gastric cancer (Colon, Rectum, Esophagus, stomach) undergoing chemotherapy were selected based on the inclusion criteria by convenience sampling. Then, Research units based on simple randomization method (Lottery Cards) were placed in intervention (30) and control group (30).

Settings and conduct

Tohid Hospital of Sanandaj

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consciousness, Age between 25-75 years, Patients with Gastrointestinal cancers (colon, rectum, esophagus, stomach), Hospitalized in the Oncology Ward of Tohid Hospital, Without fever & neutropenia. Exclusion criteria: Unwillingness to be in the study, Worsen the condition of patient, Incidence of allergic reactions.

Intervention groups

The first group, included patients in the intervention group, who received intervention with Nigella Sativa oil and the second group, included patients in the control group who received no intervention. Intervention group: after insertion of IV catheter with aseptic technique, 5 drops of Nigella Sativa oil (prepared by the pharmacist) was applied around the area of intravenous chemotherapy injection, every 12 hours (morning and night before sleep), from the first day of chemotherapy up to third day. In addition, each time before using of the oil, the place was rinsed with water. Control group: no intervention was done, only the area of the catheter was assessed for any sign of phlebitis. Then, two groups were evaluated every 12 hours over 72 hours for assessing the incidence and severity of phlebitis. The Phlebitis Visual Scale was used to assess the incidence and severity of phlebitis.

Main outcome variables

Phlebitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041892N1**

Registration date: **2018-12-26, 1397/10/05**

Registration timing: **retrospective**

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

Registration date

2018-12-26, 1397/10/05

Registrant information

Name

Niaz Behnamfar

Name of organization / entity

Islamic Azad University, Tehran Medical Branch

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 6660

Email address

niaz.behnamfar@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-04, 1397/07/12

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Nigella Sativa Oil in the Prevention of Chemotherapy- Induced Phlebitis

Public title
The Effect of Nigella Sativa Oil on Phlebitis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Consciousness & Patient cooperation Age between 25-75 years Admitted to hospital with Gastrointestinal cancer (colon, rectum, esophagus, stomach) Chemotherapeutic management with 5-fluorouracil & Oxaloplatin & Leukovein or 5-fluorouracil & Cisplatin Catheterization into arm vein Application No. 20-22 catheter Uicut Company Instructions no received antibiotic & Non-steroidal anti-inflammatory drugs Without diabetes, Skin disorders and Autoimmune diseases Stable hemodynamic status Not addiction Hospitalized in the Oncology Ward of Tohid Hospital Without fever & neutropenia
Exclusion criteria:
Unwillingness to be in the study Worsen the condition of patient during the study Incidence of allergic reactions during the study Acute infection

Age
From **25 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
in this study, Research units based on simple randomization method were placed in intervention or control group. Using Lottery Cards: two Cards for intervention group and two other Cards for control group were considered. After putting the cards in a container, a card was selected by patients and according to the selected card, patients were placed in the intervention group or control group. Then, Selected Cards were added to the other Cards in the container and a Card was taking out by patients, again. This process was done in two groups until completing the number of samples.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the patients have been blinded. In order to blind the study, the researcher was putting a cover on the container of Nigella Sativa oil, then the patients were unable to identify the oil name.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Islamic Azad University, Tehran Medical Branch

Street address

Shariati St., Khaghani St. - Islamic Azad University, Tehran Medical Sciences

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2018-03-07, 1396/12/16

Ethics committee reference number

IR.IAU.TMU.REC.1396.339

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

Every 12 hours over 72 hours after intervention

Method of measurement

observation, Visual Infusion Phlebitis Scale (VIP)

Secondary outcomes

1

Description

Pain, Erythema and Swelling

Timepoint

Every 12 hours over 72 hours

Method of measurement

Observation, Visual infusion phlebitis Scale (VIP)

Intervention groups**1****Description**

Intervention group: 5 drops of Nigella Sativa oil (prepared by the pharmacist) was rubbed around the area of intravenous chemotherapy injection, every 12 hours (morning and night before sleep), from the first day of chemotherapy up to third day, by researcher.

Category

Prevention

2**Description**

Control group: no intervention was done. Only the area of the catheters were assessed for any sign of phlebitis.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tohid Hospital of Sanandaj

Full name of responsible person

Niaz Behnamfar

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Geryashan Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr. Farshad Hashemian

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Niaz Behnamfar

Position

Master student of medical-surgical nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr. Zohreh Parsa Yekta

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Surgical Nursing

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Starting the access period from 1397

To whom data/document is available

Niaz Behnamfar

Under which criteria data/document could be used

The total potential data after unidentifiable people is for sharing analysis

From where data/document is obtainable

niaaz.behnamfar@gmail.com

What processes are involved for a request to access data/document

Print in magazine

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Niaz Behnamfar

Position

Master student of medical-surgical nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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