Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 Unicut 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

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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
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Sponsors / Funding sources

1

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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
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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
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