# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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
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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**

Tehran

**Province**

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**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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## Sponsors / Funding sources

### 1

**Sponsor**
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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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Islamic Azad University
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**Position**
Master student of medical-surgical nursing
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**