Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of "nokhod-ab" on cancer-related fatigue in cancer patients

Protocol summary

Study aim
Determine the effect of "nokhod-ab" on the fatigue of patients with cancer
Design
Clinical trial without control group, phase 3, sample size 40
Settings and conduct
This study is done in Shohaday-e-Tajrish hospital of Tehran and the type of this study is before-after. Blinding does not occur in this study.
Participants/Inclusion and exclusion criteria
Inclusion criteria: cancer-related fatigue; Age between 18- 70 years old; Hemoglobin level is at least 8g/dl; Hematocrit level at least 30%; normal TSH. Exclusion criteria: Heart disease with unstable conditions; Disabling Pulmonary Disease and History of Asthma; Severe kidney disease; Creatinine level greater than 2mg/dl; Proteinuria; The SGOT level more than 3 times of the normal threshold; Bilirubin levels greater than 2mg/dl; Positive history of hypersensitivity to saffron, cinnamon, peas; severe infection; Systemic disease; Positive history of gout or high level of uric acid; An individual who uses antidepressants due to depression; Simultaneous use of drugs that affect fatigue; Uncontrolled pain; Unwillingness to participate in the study.
Intervention groups
A group of patients with cancer-related fatigue receiving "nokhod-ab"
Main outcome variables
The mean of score of "Visual Analogue Fatigue Scale", 2. The mean of score of "Fatigue Severity Scale", 3. The mean of score of "The Cancer Fatigue Scale"

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150825023753N6**
Registration date: **2018-05-03, 1397/02/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-03, 1397/02/13**
Update count: **0**
Registration date
2018-05-03, 1397/02/13

Registrant information
Name
Mohammad Mahdi Parvizi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-05, 1396/10/15
Expected recruitment end date
2018-05-21, 1397/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of "nokhod-ab" on cancer-related fatigue in cancer patients

Public title
Effects of "nokhod-ab" on fatigue in cancerous patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Age between 18- 70 years old Patients known case of cancer Hemoglobin level is at least 8 g / dl Hematocrit level at least 30% The level of TSH is normal

Exclusion criteria:

Patients known case of heart disease with unstable conditions Disabling Pulmonary Disease and History of Asthma Patients known case of severe kidney disease Creatinine level is greater than 2mg / dl Proteinuria The SGOT level is more than 3 times of the normal threshold Bilirubin levels is greater than 2mg / dl Positive history of hypersensitivity to saffron, cinnamon, peas Uncontrolled pain, severe infection, serious illness Positive history of gout or high level of uric acid An individual who uses antidepressants due to depression Simultaneous use of drugs that affect fatigue Unwillingness to participate in the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Biomedical Research of Shahid Beheshti University of Medical sciences

Street address

Shahid Beheshti University of Medical sciences, Daneshju Blv.

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

IR.SBMU.REC.1396.51

Health conditions studied

1

Description of health condition studied

Neoplastic (malignant) related fatigue

ICD-10 code

R53.0

ICD-10 code description

Neoplastic (malignant) related fatigue

Primary outcomes

1

Description

Score of Fatigue Severity "Visual Analogue Fatigue Scale"

Timepoint

Three weeks

Method of measurement

Using Visual Analogue Fatigue Scale questionnaire

2

Description

Score of "Fatigue Severity"

Timepoint

Three weeks

Method of measurement

Fatigue Severity Scale questionnaire

3

Description

Score of "The Cancer Fatigue Scale"

Timepoint

Three weeks

Method of measurement

The Cancer Fatigue Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Administrating 80 ml "nokhod-ab" three times a day for three weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohay-e-Tahrish Hospital
Full name of responsible person
Dr Rasool Choopani
Street address
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Sponsors / Funding sources

1

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Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
Shahid Beheshti University of Medical Sciences
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ghazaleh Heydarirad
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Assistant professor
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Person responsible for updating data

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Other areas of specialty/work

Traditional Medicine

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and the result of the clinical trial

When the data will become available and for how long

6 month later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After publication of the extracted article of the clinical trial

From where data/document is obtainable

Sending Email to the researchers

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

Sending the request via the email

Comments