Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the herbal combination of Cichorium inyubus, Trigonella foenum-graecum and Foeniculum vulgare in the prevention of cancer-induced cachexia/anorexia in solid tumours' patients: a randomized, double-blinded, placebo-controlled clinical trial

Protocol summary

Study aim

The evaluation of herbal combination in the body mass index, actual body weight, arm circumference, triceps muscle circumference, Anderson, Edmonton, FAACT criteria of patients with solid tumor in comparison with placebo

Design

Two arms parallel groups, randomized trial with placebo, controlled-blinded group, and outcome assessment in 60 recruited patients between July 2018 till May 2019.

Settings and conduct

The study will be carried out in the clinic of Seyedoshohada hospital, Isfahan. The investigator will recruit the patients and devote a special code to each participant. Then, the herbal combination or placebo will be given blindly to patients for four weeks. According to the study's endpoints, patients will be followed at baseline and after four weeks of herbal combination consumption.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All adult patients with advanced solid malignant tumour who have cancer-induced anorexia or weight loss and received high doses of megestrol with no hepatic-, nephrotic- and gastrointestinal disorders.
Exclusion criteria: Patients with a known history of sensitivity to the study herbs, cardiovascular disorder, diabetes, recent major surgery, corticosteroids consumption or alcohol abuser.

Intervention groups

Patients with solid tumours who will be the candidate for receiving megestrol by a dose of 40 mg QID will be identified by physicians and investigator. The herbal combination and placebo which will be provided by Dineh company by the dose of 1 tablet three times a day for eight weeks in both patients and control group will be considered.

Main outcome variables

The considered outcomes will be included the quality of life assessment, the criteria for anorexia and weight gains such as Edmonton, Anderson, FAACT criteria as well as anthropometrics criteria such as the increase in body weight, arm muscle circumference and triceps.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040556N2**
Registration date: **2019-10-06, 1398/07/14**
Registration timing: **retrospective**

Last update: **2019-10-06, 1398/07/14**
Update count: **0**

Registration date

2019-10-06, 1398/07/14

Registrant information

Name
Azadeh Moghaddas
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 1792 7074
Email address
moghaddas@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-26, 1397/05/04

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the herbal combination of Cichorium inyubus, Trigonella foenum-graecum and Foeniculum vulgare in the prevention of cancer-induced cachexia/anorexia in solid tumours’ patients: a randomized, double-blinded, placebo-controlled clinical trial

Public title

Trigonella, Foeniculum, Chichorium in prevention of cancer-induced cachexia/anorexia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All adult patients (18 years and older) with advanced solid malignant tumour (Stage 3-4) who encountered cancer-induced anorexia or weight loss (equal or greater than 5% of the previous weight before cancer diagnosis or within the last two months). Cancer patients with serum creatinine < 2 mg /dl and serum total bilirubin < 2 mg /dl. Patients should not have any sign of dysphagia or gastrointestinal obstruction. The patients' life expectancy should be at least 3 months. Patients who are taking high doses of megestrol due to cachexia and anorexia simultaneously.

Exclusion criteria:

Patients who have undergone major surgery during the last 4 weeks. Patients with a history of thrombophlebitis diseases. Patients who have been taking systemic corticosteroid within the last 4 weeks or concurrently. Patients who have cognitive impairment, psychiatric disorder or brain metastasis leading to cognitive impairment. Patients who have diabetes, uncontrolled blood pressure or advanced heart failure (NYHA 4) Patients who are alcoholic. Patients who are pregnant or breast-feeding. Patients with a known hypersensitivity reaction to one of the plants in study herbal combination.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of sampling is based on Blocked randomization. In this method, the information about the number of treatment group, block size (multiples of group number) and the whole number of patients will be entered into internet software (https://www.sealedenvelop.com) and according to obtained codes, the type of drugs for each patient will be determined. In this study, the number of treatment groups will be 2 groups and we will use 4-containing blocks. The predicted patients' sample size will be allocated randomly according to patients' order of recruitment and special code allocation into two groups of placebo and intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, we will use the doubled-blinded randomization in which both investigator and patients will be blinded. The main investigator will allocate the concealed code to the herbal tablet or placebo according to random numbers and will provide them to investigators in charge of sampling. The investigators who are in charge of sampling will be given the herbal tablet or placebo to the patients numerically and in a blind way.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of medical Scienices, Daneshgah street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-05-15, 1398/02/25

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.117

Health conditions studied

1

Description of health condition studied
Cancer-induced cachexia
ICD-10 code
C80
ICD-10 code description
Malignant neoplasm without specification of site

Primary outcomes

1

Description
cachexia/anorexia
Timepoint
Baseline and 8 weeks later
Method of measurement
Edmonton criteria

Secondary outcomes

1

Description
Quality of life
Timepoint
Baseline and eight weeks later
Method of measurement
Iranian Version of the EORTC QLQ

Intervention groups

1

Description
Intervention group: Herbal combination including Trigonella, Foeniculum, Chichorin provided in Dineh company named Chicoridine, one tablet three times a day for eight weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo in the form of the tablet without any effective herbal combination provided in Dineh company identical to intervention group tablets, one tablet three times a day for eight weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyedoshohadda Hospital
Full name of responsible person
Azadeh Moghaddas
Street address
Daneshgah street
City
Isfehan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7074
Email
azadeh_moghaddas@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Azadeh Moghaddas
Street address
Danesghah street
City
Isfehan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7074
Email
azadeh_moghaddas@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Azadeh Moghaddas
Position
Assistant Professor

Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Isfahan University of medical Scienices, Daneshgah street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7074
Email
azadeh_moghaddas@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Azadeh Moghaddas
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Isfahan University of medical Scienices, Daneshgah street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7074
Email
azadeh_moghaddas@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Azadeh Moghaddas
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Isfahan University of medical Scienices, Daneshgah street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7074
Email
azadeh_moghaddas@yahoo.com

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
All data can be shared
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
All required analyses can be applied
From where data/document is obtainable
Azadeh Moghaddas, Clinical Pharmacy Department, School of Pharmacy, Isfahan University of Medical Sciences, Hezarjarib street, Isfahan. moghaddas@pharm.mui.ac.ir
What processes are involved for a request to access data/document
After sending a request, we will call the related person and the data will be revealed in less than one week.
Comments