

# 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 Sciences, Daneshgah street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**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

Isfahan

### Province

Isfahan

### 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

Daneshgah street

#### City

Isfahan

#### Province

Isfahan

#### 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

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**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**

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**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.

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**Email**

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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**

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**