

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Evaluation of herbal combination consists of Trigonella, Foeniculum, Chichorium, Hornleum and Glycine in the prevention of cancer-induced cachexia/anorexia of solid tumors' patients: a randomized, double-blinded, placebo-controlled clinical trial

#### Protocol summary

##### Study aim

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

##### Design

Two arms parallel group 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

All adult patients with advanced solid tumor malignancies who have cancer-induced anorexia or weight loss and received high doses of megestrol with no hepatic-, nephrotic- and gastrointestinal disorders. Patients with a known history of assessed herbal combination, cardiovascular disorder, diabetes, recent major surgery, taken corticosteroids or alcohol abuser will be excluded.

##### Intervention groups

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

#### Main outcome variables

The considered outcomes will be included, demographic patients characteristics, quality of life assessment, the criteria for anorexia and weight gain 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: **IRCT20180722040556N1**

Registration date: **2019-05-28, 1398/03/07**

Registration timing: **retrospective**

Last update: **2019-05-28, 1398/03/07**

Update count: **0**

##### Registration date

2019-05-28, 1398/03/07

##### 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**

2019-03-15, 1397/12/24

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of herbal combination consists of Trigonella, Foeniculum, Chichorium, Hornleum and Glycine in the prevention of cancer-induced cachexia/anorexia of solid tumors' patients: a randomized, double-blinded, placebo-controlled clinical trial

**Public title**

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

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

All adult patients (18 years and older) with advanced solid tumor malignancies (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. Cancer patients with serum total bilirubin < 2 mg / dl. Patients haven't had any sign of dysphagia or gastrointestinal obstruction. We have expected patients to be alive at least 3 upcoming months. Patients who have received high doses of megestrol due to cachexia and anorexia simultaneously.

**Exclusion criteria:**

Patients who have undergone major surgery for 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 have consumed chronic alcohol. Patients who are pregnant or breast-feeding. Patients with a known hypersensitivity reaction to one of the plants in considered herbal combination

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the randomization will be carried out according to simple randomization via the random numbers obtained by Excell software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, we will use the doubled-blinded randomization in which both investigator and included patients will be blinded.

**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**

Daneshgah street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2018-11-11, 1397/08/20

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1398.118

**Health conditions studied****1****Description of health condition studied**

Cancer-induced cachexia

**ICD-10 code**

C80.9

**ICD-10 code description**

C80.0

**Primary outcomes****1****Description**

Evaluation of herbal combination consists of Trigonella, Foeniculum, Chichorium, Hornleum, and Glycine in the prevention of cancer-induced cachexia/anorexia

**Timepoint**

Baseline and 4 weeks later

**Method of measurement**

Edmonton criteria

**Secondary outcomes****1****Description**

Quality of life

**Timepoint**

Baseline and four weeks later

**Method of measurement**

Iranian Version of the EORTC QLQ

**Intervention groups****1****Description**

Intervention group: Herbal combination including Trigonella, Foeniculum, Chichorium, Hornleum, and Glycine provided in Dineh company named General Tonic, one sachet three times a day for four weeks

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Seyedoshohadda Hospital

**Full name of responsible person**

Azadeh Moghaddas

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Daneshgah street

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azadeh\_moghaddas@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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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**

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**

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**Full name of responsible person**

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**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

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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**