

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Explanation of chronic renal failure and its complications according to Iranian Traditional Medicine and the effect of plant Heilichrysum pseudoplicatum capsule on anorexia and pruritus in hemodialysis patients

#### Protocol summary

##### Study aim

The effect of Heilichrysum pseudoplicatum capsule on anorexia and pruritus in patients undergoing hemodialysis

##### Design

This is a clinical trial. In this study, there are two groups of control ( who receive placebo ) and the intervention group (receiving Heilichrysum pseudoplicatum capsule). The number of people in each group is thirty-five. The study is triple blind: participants, therapeutic staff, and statistical analyst of data and drugs are blinded.

##### Settings and conduct

This study is done in a supportive center for supportive dialysis in Arak. This study was carried out by a researcher and three-blind medical personnel.

##### Participants/Inclusion and exclusion criteria

The hemodialysis patients with questionnaire score<14 written and informed satisfaction of patients

##### Intervention groups

Dialysis patients who have the criteria for entering the study are randomly divided into two groups then,Then for 6 weeks the patients in the intervention group will receive the Heilichrysum pseudoplicatum capsule and the control group will receive placebo.

##### Main outcome variables

Anorexia; pruritus

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180610040049N2**

Registration date: **2020-03-24, 1399/01/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-24, 1399/01/05**

Update count: **0**

##### Registration date

2020-03-24, 1399/01/05

##### Registrant information

###### Name

Amirhosein Latifi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3601

###### Email address

Sah.latifi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-19, 1398/11/30

##### Expected recruitment end date

2020-05-20, 1399/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Explanation of chronic renal failure and its complications according to Iranian Traditional Medicine and the effect of plant Heilichrysum pseudoplicatum capsule on anorexia and pruritus in hemodialysis patients

##### Public title

Effect of plant Heilichrysum pseudoplicatum capsule on

anorexia and pruritus in hemodialysis patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Be on hemodialysis treatment for at least three months  
Anorexia questionnaire score less than 14

### Exclusion criteria:

Patient's willingness to use other therapies  
Diabetic patients

## Age

From **30 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Data analyser

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The block randomization method with 4, 6 and 8 block sizes will be used to assign people to the two groups. Concealment will also be observed by using this method. In this way, each individual is assigned a unique code and is attached to drug packages that will help the blind process.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

In this three-blind study, patient and therapeutic personnel and data analyst do not have any type of data and medications. The drugs are encoded and placed on the patient and medical personnel.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Arak University of Medical Sciences, Basij Square

##### City

Arak

## Province

Markazi

## Postal code

3848176941

## Approval date

2020-03-08, 1398/12/18

## Ethics committee reference number

IR.ARAKMU.REC.1397.54

## Health conditions studied

### 1

#### Description of health condition studied

Dialysis patients

#### ICD-10 code

T81.502

#### ICD-10 code description

Unspecified complication of foreign body accidentally left in body following kidney dialysis

## Primary outcomes

### 1

#### Description

Appetite

#### Timepoint

One day before the intervention and one day after the intervention is measured

#### Method of measurement

Appetite level with SNAQ questionnaire

### 2

#### Description

Pruritus rate

#### Timepoint

One day before the intervention and one day after the intervention is measured

#### Method of measurement

Pruritus severity with Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: the Heilichrysum pseudoplicatum plant capsule is given to the intervention group. Helichrysum is a family of wormwood. The total extract of this plant is used. The dose is 250 mg / kg. For 6 weeks, take one capsule after dinner. These capsules are manufactured by Barij Essence and Pharmacy Department of Shahid Beheshti University.

#### Category

Treatment - Drugs

## 2

### Description

Control group: the placebo capsule is given to the control group. Placebo capsules have the same size and shape as the drug. And their contents contain corn starch. These capsules are manufactured by Barij Essence and Pharmacy Department of Shahid Beheshti University.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The Half-State Center for Supportive Dialysis in Arak(Hami)

##### Full name of responsible person

Seied Amirhosein Latifi

##### Street address

Arak University of Medical Sciences, Basij Square

##### City

Arak

##### Province

Markazi

##### Postal code

3848176341

##### Phone

+98 86 3417 3645

##### Email

seiedalatifi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Alireza Kamali

##### Street address

Arak University of Medical Sciences, Basij Square

##### City

Arak

##### Province

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##### Postal code

3848176941

##### Phone

+98 86 3417 3645

##### Email

seiedalatifi@yahoo.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

No

##### Title of funding source

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Seied Amirhosein Latifi

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Arak University of Medical Sciences, Basij Square

##### City

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## Person responsible for scientific inquiries

#### Contact

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Arak University of Medical Sciences

##### Full name of responsible person

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**Province**

Markazi

**Postal code**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable