

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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