

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of effect of hydroalcoholic extract of trifolium plant in patients with subclinical hypothyroidism

Protocol summary

Study aim

Evaluation of effect of hydroalcoholic extract of trifolium plant in patients with subclinical hypothyroidism

Design

This clinical trial was performed on 40 patients, divided into two groups of 20, including a control group and parallel groups. This study is blinded and simple randomization is used.

Settings and conduct

The field of work is clinical - internal. This study is performed in the Tohid Hospital in Sanandaj. The intervention group is given a 500 mg capsule of hydroalcoholic extract of trifolium plant daily for three months, along with standard treatment. The control group is also given a daily placebo for three months, along with standard treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with lately diagnosed subclinical hypothyroidism

Intervention groups

Intervention group: hydroalcoholic extract of trifolium plant, oral capsule, 500 mg, Once a day for three months with standard treatment Control group: placebo containing starch, oral capsule, 500 mg, Once a day for three months with standard treatment

Main outcome variables

Serum TSH levels; Serum T4 levels; Serum T3 levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043279N3**

Registration date: **2020-05-24, 1399/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2025-11-05, 1404/08/14**

Update count: **1**

Registration date

2020-05-24, 1399/03/04

Registrant information

Name

Pezhman Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 87 3324 9435

Email address

p.sharifi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of hydroalcoholic extract of trifolium plant in patients with subclinical hypothyroidism

Public title

Evaluation of effect of trifolium plant on hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lately diagnosed subclinical hypothyroidism

Exclusion criteria:

Thyroiditis Pregnancy Cardiovascular disease Thyroid cancer Recent surgery Blood disorders children Breastfeeding chronic Diseases Dissatisfaction patients to participate in the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method with a block size of 4. Sampling method at this study will be according to random allocation. Participants will enter the study according to inclusion criteria, and then will be divided into two groups according to randomization table. One group will receive (Capsule containing hydroalcoholic extract of trifolium plant) and the other will receive placebo. The participants and administrator do not have any information about content of capsules (double blinded study). The list of randomization was computer-generated. supplements and placebo capsules were placed in completely identical packages and were coded by someone who was unaware of the nature of the study in numbered bottles based on the list. And another person who was unaware of the contents of the pack provided them to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All supplements and placebo capsules were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.MUK.REC.1397/384

Health conditions studied

1

Description of health condition studied

Subclinical hypothyroidism

ICD-10 code

E02

ICD-10 code description

Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description

Serum TSH levels

Timepoint

Measurement of TSH levels before the intervention and three months later

Method of measurement

Serum level evaluation

2

Description

Serum T4 levels

Timepoint

Measurement of T4 levels before the intervention and three months later

Method of measurement

Serum level evaluation

3

Description

Serum T3 levels

Timepoint

Measurement of T3 levels before the intervention and three months later

Method of measurement

Serum level evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsule containing hydroalcoholic extract of trifolium plant at a dose of 500 mg per day for three consecutive months. These oral capsules of trifolium plant are prepared by a reputable pharmacist.

Category

Placebo

2

Description

Control group: Placebo in capsules at a dose of 500 mg per day for three consecutive months. These placebo oral capsules contain starch and are prepared by a reputable pharmacist.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital

Full name of responsible person

Shahnaz Ghafouri

Street address

Tohid Hospital, Geriashan Ave

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Sanandaj

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Postal code

6616812131

Phone

+98 87 3366 4645

Email

drghafoorish76@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr. Afshin Maleki

Street address

Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Shahnaz Ghafouri

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology and Metabolism

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Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran

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Person responsible for updating data**Contact****Name of organization / entity**

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

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable