

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Assessment of the effect of hydroalcoholic extract of *Portulaca oleracea* on thyroid hormones in hyperthyroidism

Protocol summary

2020-07-11, 1399/04/21

Study aim

Evaluation of effect of hydroalcoholic extract of *Portulaca oleracea* on thyroid hormones in hyperthyroidism

Design

This clinical trial was performed on 50 patients, divided into two groups of 25, including a control group and parallel groups. This study is Double-blind and block randomization method is used.

Settings and conduct

The field of work is clinical - internal. This study is performed in the Tohid Hospital in Sanandaj. Patients, physicians, and nurses who evaluate the outcomes will be blind to the groups studied.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with recently diagnosed hyperthyroidism
Exclusion Criteria: pregnancy, children, cardiovascular disease, Thyroiditis, Ophthalmopathy

Intervention groups

Intervention group: hydroalcoholic extract of *Portulaca oleracea*, oral capsule, 400 mg, Three times a day for two months with standard treatment
Control group: placebo containing starch, oral capsule, 400 mg, OThree times a day for two months with standard treatment

Main outcome variables

Serum TSH levels; Serum T4 levels; BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043279N5**

Registration date: **2020-07-11, 1399/04/21**

Registration timing: **prospective**

Last update: **2020-07-11, 1399/04/21**

Update count: **0**

Registration date

Registrant information

Name

Pezhman Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3324 9435

Email address

p.sharifi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of hydroalcoholic extract of *Portulaca oleracea* on thyroid hormones in hyperthyroidism

Public title

Assessment of the effect of *Portulaca oleracea* on hyperthyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Recently diagnosed hyperthyroid patients

Exclusion criteria:

Pregnancy Children Cardiovascular disease
Ophthalmopathy Thyroiditis

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: **50**

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 *Portulaca oleracea*) and the other will receive placebo. Individuals are the randomization unit, making a random sequence is by using statistical software (WinPepi11.0). Allocation concealment is by assigning unique codes

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
2019-07-10, 1398/04/19
Ethics committee reference number
IR.MUK.REC.1398.092

Health conditions studied

1

Description of health condition studied

Hyperthyroidism

ICD-10 code

E05.9

ICD-10 code description

Thyrotoxicosis, unspecified

Primary outcomes

1

Description

Serum TSH levels

Timepoint

Measurement of TSH levels before the intervention and two months later

Method of measurement

ELISA

2

Description

Serum T4 levels

Timepoint

Measurement of T4 levels before the intervention and two months later

Method of measurement

ELISA

3

Description

Serum T3 levels

Timepoint

Measurement of T3 levels before the intervention and two months later

Method of measurement

ELISA

4

Description

Body Mass Index

Timepoint

Measurement of BMI before the intervention and two months later

Method of measurement

According to the BMI formula (BMI = (weight in

kilograms) divided by (Height in meters squared))

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsule containing hydroalcoholic extract of *Portulaca oleracea* plant at dose of 400 mg three times a day for two consecutive months. These oral capsules of hydroalcoholic extract of *Portulaca oleracea* plant are prepared by a reputable pharmacist.

Category

Placebo

2

Description

Control group: Placebo in capsules at dose of 400 mg three times a day for two 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

City

Sanandaj

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Kurdistan

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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Email

maleki43@yahoo.com

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 scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

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Person responsible for updating data

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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