

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Evaluation the effect of thyrophyte herbal composition on the weight of patients with primary hypothyroidism

Protocol summary

Study aim

Evaluation the effect of thyrophyte herbal composition on the weight of patients with primary hypothyroidism

Design

This study is a Randomized clinical trial, containing intervention and control groups with parallel groups and triple-blind. The random allocation sequence conduct by using the random numbers table and randomization.com site. The method of allocation concealment is sealed envelope. Patients, researcher and analyzer are unaware of the individuals assigned to the groups. The sample size is 40 people in each group.

Settings and conduct

80 primary hypothyroid patients with overweight and eligibility are selected by the endocrinologist from the endocrinology and metabolism clinic of Ghaem Hospital. Demographics, history , weight of patients are registered . tests (thyroid hormones, lipid profile, fasting sugar) are requested. WHO Quality of Life Questionnaire and Beck Depression Questionnaire are completed by patients. they are randomly divided into two parallel groups of intervention and control and enter the study for 8 weeks. Weight measurement, tests and questionnaires are also done at the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Age: 20 to 65 years, Patients known to have primary hypothyroidism by an endocrinologist, Hypothyroid patients with overweight or obesity whose weight has not been controlled with levothyroxine. Exclusion criteria : Uncontrolled systemic diseases Any diet for weight loss during the study and 3 months before arrival Take a vitamin supplement at least three months before or during the study Patient dissatisfaction with continued cooperation Pregnancy Lactation

Intervention groups

Intervention group : levothyroxine and herbal composition (4.5 g / day in 6 capsules 750 mg) Control group : levothyroxine and placebo capsule

Main outcome variables

Weight

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210101049909N1**

Registration date: **2021-06-18, 1400/03/28**

Registration timing: **prospective**

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

Registration date

2021-06-18, 1400/03/28

Registrant information

Name

Najme Javidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3876 0995

Email address

javidin9711@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of thyrophyte herbal composition on the weight of patients with primary hypothyroidism

Public title

The effect of thyrophyte herbal composition on the weight of patients with primary hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 20 to 65 years Patients known to have primary hypothyroidism by an endocrinologist Hypothyroid patients with overweight or obesity whose weight has not been controlled with levothyroxine

Exclusion criteria:

Uncontrolled systemic diseases Any diet for weight loss during the study and 3 months before arrival Take a vitamin supplement at least three months before or during the study Patient dissatisfaction with continued cooperation Pregnancy Lactation

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into Intervention and control groups in blocked randomization model by using the random numbers table and randomization.com site. The method of allocation concealment is sealed envelope .

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, researcher and analyzer are unaware of the individuals assigned to the intervention and control group. Only the sample assignor to the groups is aware of the control and intervention group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad Univercity Of Medical Sciences, University StreetThe Ethics Committee of Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.MUMS.REC.1400.037

Health conditions studied

1

Description of health condition studied

Hypothyroidy

ICD-10 code

(E00-E90)

ICD-10 code description

Ectopic endocrine tissue or hyperfunction and hypofunction of endocrine glands associated with neoplasms and other conditions classified elsewhere

Primary outcomes

1

Description

Weight

Timepoint

Before and after intervention

Method of measurement

To measure weight, calculate the ratio of weight in kilograms to height squared in meters (body mass index) and calculate the ratio of waist to hip in centimeters (WHR) using weight and tape meters.

Secondary outcomes

1

Description

Lipid profile

Timepoint

Before and after intervention

Method of measurement

By blood test in mg/dl

2

Description

Fasting blood sugar

Timepoint

Before and after intervention

Method of measurement

By blood test in mg/dl

3

Description

Thyroid hormone (TSH, FT4, T3)

Timepoint

Before and after intervention

Method of measurement

By blood test in ng/dl

4

Description

Depression score on Beck Depression questionnaire

Timepoint

Before and after intervention

Method of measurement

Beck Depression questionnaire

5

Description

Quality of Life score on WHO Quality of Life Questionnaire

Timepoint

Before and after intervention

Method of measurement

WHO Quality of Life Questionnaire

Intervention groups

1

Description

Intervention group: They receive levothyroxine and herbal composition (nigella sativa, trachyspermum ammi, citrus aurantifolia) at a dose of 4.5 g daily in 6 capsules of 750 mg for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: They receive Levothyroxine and placebo (Avisel) capsule for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and Metabolism Clinic of Ghaem Hospital

Full name of responsible person

Zahra Mazloun Khorasani

Street address

Ahmadabad Street, Ghaem Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences, Building Qureshi, Daneshgah Ave

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Phone

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Email

vcresearch@mums.ac.ir

Web page address

<http://v-research.mums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Najme Javidi

Position

PhD student of Iranian Traditional and Complementary Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

School of Traditional and Complementary Medicine, Ferdosi University Campus, Azadi Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahdi Yousefi

Position

Assistant Professor

Latest degree

Ph.D.

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Person responsible for updating data

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Position

PhD student of Iranian Traditional and Complementary Medicine

Latest degree

Medical doctor

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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

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

Analytic Code

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

Data Dictionary

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