Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Nov 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 Mazloum 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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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

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

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assistant Professor

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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
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