Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

investigating the effect of Ardor syrup (Persian medicine formulation based on Rosa dumascena) on symptoms and thyroid profile of women with subclinical hypothyroidism

Protocol summary

Study aim
Determining the effect of Iranian medicine formula on fatigue intensity and TSH in women with subclineal thyroid hypothyroidism

Design
Clinical trial with control group, double-blind, randomized, phase 3 on 60 patients with Random allocation rule

Settings and conduct
This study will be performed on 60 people with subclinical hypothyroidism who are refered to Touba specialized clinic in Sari, who after applying the inclusion and exclusion conditions and completing the informed consent form with a random allocation process in one of the groups: Intervention and control.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All women over the age of 18 with subclinical hypothyroidism Non-entry criteria: Pregnancy and lactation; chronic underlying disease that affects symptoms (such as kidney disease, diabetes and heart failure); Dissatisfaction with the plan; History of allergy to herbal medicines; Addiction; Taking other herbal medicines Exclusion criteria: Pregnancy; Unwillingness and uncooperation to participate in the project at any time; Not takeing medication regularly for at least one week (7 days); Any side effects; Any disease that requires new therapeutic and pharmacological interventions.

Intervention groups
Intervention group: levothyroxine + ardor syrup for 2 months Placebo group: levothyroxine + placebo syrup (with the same form and amount of medicine per day will be determined).

Main outcome variables
TSH; Free T4; Free T3

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220920056005N1**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

Registration date
2023-08-30, 1402/06/08

Registrant information

Name
Fatemeh Ghaffari Saravi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3324 3117

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f.ghaffari@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2025-06-22, 1404/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
investigating the effect of Ardor syrup (Persian medicine formulation based on Rosa dumascena) on symptoms and thyroid profile of women with subclinical hypothyroidism

Public title
The effect of Iranian medicine formula on subclinical hypothyroidism
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All women over18 years of age suffering from subclinical hypothyroidism .
Exclusion criteria:
Pregnancy lactation People with chronic underlying disease that affects symptoms (such as kidney disease, patients with diabetes and heart failure) Dissatisfaction with the plan History of allergy to herbal medicines Addiction Taking other herbal medicines
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples are randomly assigned into two groups. Random allocation method will be done by blocking method. The blocking process will be done with Random allocation software. With this software, 10 blocks of 6 will be produced. Samples will be included in the study based on the produced blocks.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study was designed as a triple blind so that physician, patient, evaluator, consultant colleague of statistics, etc. will be completely unaware of the intervention type (drug or placebo). The placebo will be made quite similar to the drug (appearance, packaging, color and smell.)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Moallem square, Moallem avenue
City
Sari
Province
Mazandaran
Postal code
4816895474
Approval date
2023-04-19, 1402/01/30
Ethics committee reference number
IR.MAZUMS.REC.1402.021

Health conditions studied

1

Description of health condition studied
Subclinical hypothyroidism
ICD-10 code
E03.9
ICD-10 code description
Hypothyroidism, unspecified

Primary outcomes

1

Description
TSH
Timepoint
Before the intervention, day 56 after the intervention
Method of measurement
Lab test

2

Description
Free T4
Timepoint
Before the intervention, day 56 after the intervention
Method of measurement
Lab test

3

Description
Free T3
Timepoint
Before the intervention, day 56 after the intervention

Method of measurement
Lab test

Secondary outcomes

1

Description
BMI
Timepoint
Before the intervention, day 56 after the intervention
Method of measurement
Weight by a scale in kilograms and height in centimeters and calculation

2

Description
Fatigue
Timepoint
Before the intervention, day 56 after the intervention
Method of measurement
fatigue severity scale (fss)

Intervention groups

1

Description
Routine treatment (levothyroxin) + Consumption of Persian medicine formulation (Arder syrup, 5 cc every 12 hours until one hour after meals. (Arder syrup consists of Pimpinella anisum seed, Foeniculum vulgare seed, Apium graveolens seed, Rosa damascene petal and Crocus sativus stigma.) for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Routine treatment (levothyroxin) + Consumption of Placebo syrup for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghban Subspecialty Clinic (Touba)
Full name of responsible person
Dr Assie Jokar
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Khazar Bolvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Pedram Ebrahimnejad
Street address
Deputy of Research and Technology Mazandaran University of Medical Sciences, Moalem Ave., Moalem Square
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Assie Jokar
Position
Associate 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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Position
Resident

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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