

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

investigating the effect of Ardor syrup (Persian medicine formulation based on *Rosa damascena*) 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 subclinical 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 referred to Toubia 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 taking 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)

Phone

+98 11 3324 3117

Email address

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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 over 18 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

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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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Center for Traditional Medicine and Complementary
Medicine of mazandaran university; Khazar
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Ghaffari Saravi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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