

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of Therapeutic Effect of glucosinolate extract of *Descurainia sophia* (L.) Webb ex Prantl on the improvement of patients with hyperthyroidism who are treated with methimazole; Pilot study Double Blinded and Placebo-Controlled Clinical Trial

Protocol summary

Checking of Improvement in Patients with hyperthyroidism

Study aim

Determination of the therapeutic effect of Glucosinolate extracts on the improvement of hyperthyroidism

Design

This study will be done in Double Blinded and prospective and Placebo-Controlled Clinical Trial. Sixteen female patients were selected among the referrers to Endocrine clinic of Mazandaran University of Medical Sciences and randomly divided into two groups, the first group received methimazole 10 to 20 mg daily with placebo capsules and the second group received methimazole with a dose of 10 to 20 mg daily with a capsule containing a seed extract at a dose of 350 mg daily. To randomize the division of patients, we divide the patients into the two groups according to the Row of Presence at the clinic, patients are divided into two groups using the random numbers table.

Settings and conduct

the study does under the supervision of a Endocrinologist at touba medical center . The randomized coded products are given to patients.

Participants/Inclusion and exclusion criteria

Patients by the age ranging 20 and 60 years Patient without a history of underlying illness such as heart failure, diabetes, and hypertension No smoking Lack of alcohol No pregnancy or breastfeeding No anti-thyroid medication in the last three months Lack of ALT level is more than normal level of Ft4 =1.8-7.7ng/ml or 23-100pmol/l TSH<0.4

Intervention groups

The study consists of two groups of placebo and drug recipients .The intervention group received a capsule containing the extract and the placebo or control group received an extract-free capsule. Capsules are taken daily by the individual.

Main outcome variables

General information

Reason for update

Acronym

ETEDH

IRCT registration information

IRCT registration number: **IRCT20130911014630N6**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Mohammad Azadbakht

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3728

Email address

mazadbakht@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-24, 1398/03/03

Expected recruitment end date

2021-03-02, 1399/12/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Therapeutic Effect of glucoseinolate extract of Descurainia sophia (L.) Webb ex Prantl on the improvement of patients with hyperthyroidism who are treated with methimazole; Pilot study Double Blinded and Placebo-Controlled Clinical Trial

Public title
Evaluation of Therapeutic Effect of Descurainia sophia on the patients with hyperthyroidism

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between twenty to sixty years Patients with a higher level of FT4 hormones have a parity of 17 pg /L Patients with a FT3 serum level Larger than equal to 5.7 pg/ml Patients with a lower serum TSH level equal to MU / 10.4
Exclusion criteria:
Patients with a history of underlying illness, such as diabetes or hypertension or liver failure, such as cirrhosis of the liver and kidney or heart disease, according to patients referenced Use other medications Use cigarettes right now Alcoholism Pregnant patients Lactating patients Patients who have taken an antithyroid drug for the last three months Patient with ALT levels are twice the normal range Patients who are required to receive other medications for the treatment of other illness during the study Patients who experience side effects such as itching or headache or allergies to the drug Requesting a patient or his family to leave the study

Age
From **20 years** old to **60 years** old

Gender
Female

Phase
0

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description
First, we divide the patients into the two groups according to the number of attending the clinic and using the random number table.

Blinding (investigator's opinion)
Double blinded

Blinding description
According to the code assigned to each of the products in the previous stage, we assign a code to each patient so that the patient and the doctor are not aware of the type of capsule they are consuming.

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
Moalem sq. Mazandaran University of Medical Science
City
Sari
Province
Mazandaran
Postal code
4847191971

Approval date
2019-05-01, 1398/02/11

Ethics committee reference number
IR.MAZUMS.REC.1398.360

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
Level of thyroid hormones

Timepoint
First of the study (before the intervention) and 30, 60 and 90 days after the start of the capsule

Method of measurement
Collection of questionnaires and laboratory tests and periodic clinical examinations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: methimazole with a dose of 10 to 20 mg per day plus a capsules containing 350 mg of extract of the plant during 3months

Category

Treatment - Drugs

2

Description

Control group: methimazole with a dose of 10 to 20 mg per day plus placebo capsules during 3months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba Medical Center - Mazandaran University of Medical Science

Full name of responsible person

Dr. Mohammad Azadbakht - Dr.Zahra Kashi

Street address

Tuba Medical Center, Farah Abad Square , Khazar Boulevard , Sari , Mazandaran , Iran

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Azadbakhtm@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Majid Saedi

Street address

Mazandaran University of Medical Science

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Province

Mazandaran

Postal code

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Phone

Email

majsaeedi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Fatemeh Farzameh

Position

Pharmacy student of Sari Pharmaceutical School

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Mazandaran

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohamad Azadbakht

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Results from clinical trials

When the data will become available and for how long

Start access after printing the article

To whom data/document is available

Access for scholars working in academic institutions

Under which criteria data/document could be used

Use of results is allowed only by mentioning its source

From where data/document is obtainable

azadbakhtm@hotmail.com

What processes are involved for a request to access data/document

Request from the researcher

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Farzameh

Position

Pharmacy Student Of Pharmacy College -Sari

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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College - Sari