Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

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 and60 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

Checking of Improvement in Patients with hyperthyroidism

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 Scinecee

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 / l0.4

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 plusplacebo 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
City
Sari
Province
Mazandaran
Postal code
48188-69378
Phone
+98 11 3354 2472
Email
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
City
Sari
Province
Mazandaran
Postal code
48188-69378
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
Street address
Iran, Mazandaran province, Sari city,Prophet Mohammad Medical Sciences Complex,Mazandaran faculty of pharmacy
City
Sari
Province
Mazandaran
Postal code
-
Phone
.
Fax
Email
atena.farzameh1997@gmail.com
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
Street address
Iran,Mazandran province,sari city,Prophet Mohammad Medical Sciences Complex,Mazandaran faculty of pharmacy
City
Sari
Province
Mazandaran
Postal code
48188-69378
Phone
+98 911 151 3032
Fax
Email
Mazadbakht@gmail.com
Web page address

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
Street address
Payambar Azam Medicinal Complex-Pharmacy College - Sari
City
Sari
Province
Mazandaran
Postal code
48188-69378
Phone
+98 33113555
Email
atena.farzameh1997@gmail.com

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