

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Evaluation the effectiveness of administering levothyroxine in morning versus evening on thyroid factor number 4 and thyroid stimulating hormon in sari hypothyroid patients

Protocol summary

Summary

In this study, administering of levothyroxine sodium for hypothyroid patients in morning versus evening is evaluating. The main objective of this study is to determine consuming the levothyroxine in the morning has better effect or in the evening? During the study 50 patients that come to the Endocrinology clinic in sari city of Iran for treatment of hypothyroidism will enter to the study and each patient will get 2 pills every day. One pill is levothyroxine and the other is placebo. Placebo contains levothyroxine exipients with no effective substance. The drug's dose that each patient intake is administering by doctor. This study is crossover. 2 group with 25 people are chosen accidentally. The first group takes levothyroxine in the morning and placebo in the evening and the second one takes levothyroxine in the evening and placebo in the morning; After 2 month tow group will exchange together. Before starting the treatment, at the end of the first 2 month and at the end of 4 month, thyroid factors will be checked. Finally results will be compared and analyzed statistically in each group and between groups. During the study a request form including all of the patient's identification is filled. Primary end point contains obvious changing in thyroid factor number 4 and thyroid stimulating factor. Secondary end point contains removing the primary complaint, changing in weight, blood pressure and efficacy of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903223014N2**
Registration date: **2011-04-10, 1390/01/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-04-10, 1390/01/21

Registrant information

Name

Shahram Ala

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1354 3083

Email address

sala@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of administering levothyroxine in morning versus evening on thyroid factor number 4 and thyroid stimulating hormon in sari hypothyroid patients

Public title

Evaluation of administering levothyroxine in morning versus evening in Sari hypothyroid patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: patients with hypothyroidism, up to 18

Exclusion: pregnant, GI problems, drugs which interact with levothyroxine

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics department of Mazandaran University of Medical Sciences

Street address

Ethics department of Mazandaran University of Medical Sciences, Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, sari, Mazandaran, Iran

City

Sari

Postal code**Approval date**

2010-01-25, 1388/11/05

Ethics committee reference number

200

Health conditions studied**1****Description of health condition studied**

hypothyroidism

ICD-10 code

E00-E07

ICD-10 code description

thyroid gland disorders

Primary outcomes**1****Description**

TSH

Timepoint

every 2 month

Method of measurement

with lab kit

2**Description**

T4

Timepoint

every 2 months

Method of measurement

with lab kit

Secondary outcomes**1****Description**

primary complaint

Timepoint

every 2 months

Method of measurement

request form

2**Description**

changing in weight

Timepoint

Every 2 month

Method of measurement

request form

3**Description**

Efficacy of life

Timepoint

Every 2 month

Method of measurement

Request form

Intervention groups**1****Description**

During the study 50 patients who are going to the endocrinology clinic of Sari for treating their

hypothyroidism enter to the study. These people divided in two 25people group. During the first 2 month the first group takes levothyroxine 30 minute before breakfast. Intake dose for each person is determined by doctor. Then during the second two month patients take levothyroxine 30 minute before dinner in the evening. For the second group taking levothyroxine during the first and second 2 month will cross over.

Category

Treatment - Drugs

2

Description

During the study 50 patients who are going to the endocrinology clinic of Sari for treating their hypothyroidism enter to the study. These people divided in two 25people group. Each group should take placebo one time a day. Placebo contains all of the levothyroxine exipients without effective substance. During the first 2 month the first group takes placebo in the evening, 30 minute before dinner. Intake dose for each person is similar to levothyroxine that is consumed per day. Then during the second two month patients take placebo in the morning, 30 minute before breakfast. For the second group taking levothyroxine during the first and second 2 month will cross over.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

tooba special clinic

Full name of responsible person

Neda Sasanpour

Street address

Tooba special clinic, Khazar street, Sari, Iran

City

sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Vice chancellor for research of Mazandaran university pharmacy college, Dr Shahram ala

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, Sari, Mazandaran, Iran

City

Sari

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, Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Neda Sasanpour

Position

Pharmacy student

Other areas of specialty/work

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, Sari, Mazandaran, Iran

City

Sari

Postal code

Phone

+98 31 1234 6378

Fax

Email

sasanpoorneda@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Dr shahram Ala

Position

Clinical pharmacy specialist, Associated professor

Other areas of specialty/work

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, Sari, Mazandaran, Iran

City

Sari

Postal code
Phone
+98 15 1354 3083
Fax
+98 15 1354 3084
Email
sh204ala@yahoo.com
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty