

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of levothyroxine on glucose metabolism in hypothyroid patients aged 18-65 years

Protocol summary

Study aim

The effect of levothyroxine treatment on glucose metabolism in patients with hypothyroidism

Design

Non randomized clinical trial, without control group, before and after exposure assessment

Settings and conduct

This clinical trial include samples who are newly diagnosed with hypothyroidism and who have indications of levothyroxine therapy referred to the endocrinology clinic of Tabriz Imam Reza Hospital. The total sample size is 40. Fasting serum insulin and glucose levels and lipid profiles in all participants will be assessed at baseline and three months after levothyroxine treatment.

Participants/Inclusion and exclusion criteria

inclusion criteria: All newly diagnosed hypothyroidism needs treatment in the age range of 18 to 65 years
exclusion criteria: Patients with diabetes mellitus, hypertension, heart failure, liver and kidney disease and polycystic ovary syndrome, treatment with levothyroxine, statins and OCPs in the last 3 months, pregnancy and lactation

Intervention groups

Patients with hypothyroidism requires treatment in the age range of 18 to 65 years

Main outcome variables

Body Mass Index; Thyroid Function Tests; Insulin Resistance; Lipid Profile; Anti TPO Ab Level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130610013612N10**

Registration date: **2019-09-02, 1398/06/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

Registration date

2019-09-02, 1398/06/11

Registrant information

Name

Farzad Najafipour

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7850

Email address

najafipourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-01, 1398/05/10

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of levothyroxine on glucose metabolism in hypothyroid patients aged 18-65 years

Public title

effects of levothyroxin on glucose metabolism in patients with hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All newly diagnosed hypothyroidism require treatment in the age range of 18 to 65 years

Exclusion criteria:

Patients with diabetes mellitus, hypertension, heart failure, liver and kidney disease and polycystic ovary syndrome Treatment with levothyroxine, statins and OCPs in the last 3 months Pregnancy and lactation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

کمیته محترم اخلاق دانشگاه علوم پزشکی تبریز

Street address

Ethics Committee, Tabriz University of Medical Sciences, Golgasht Street , Tabriz

City

tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2019-07-13, 1398/04/22

Ethics committee reference number

IR.TBZMED.REC.1398.457

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

Hypothyroidism

ICD-10 code

E03.9

ICD-10 code description

Hypothyroidism, unspecified

2**Description of health condition studied**

insulin resistance

ICD-10 code

R73.02

ICD-10 code description

Impaired glucose tolerance (oral)

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

insulin resistance

Timepoint

Baseline, three months after treatment

Method of measurement

Fasting plasma glucose, fasting plasma insulin, HOMA IR(Hemostasis model assessment), QUICKI(Quantitative insulin sensitivity check index)

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

body mass index

Timepoint

At baseline and three months after treatment

Method of measurement

body weight, height

2**Description**

lipid profile

Timepoint

At baseline and three months after treatment

Method of measurement

serum fasting levels of triglycerides, cholesterol, HDL(high density lipoprotein) and LDL(low density lipoprotein)

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

Treatment with levothyroxine tablet (Iran hormone) 1.7 micrograms per kg body weight daily for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrine Clinic of Imam Reza Hospital
Full name of responsible person
Taher manzary MD
Street address
Azadi Blvd., Golgasht Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 8939
Email
manzarytaher@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
دکتر ابوالقاسم جویبان
Street address
Vice chancellor for Research, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3335 7310
Email
research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Farzad Najafipour
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Department of Endocrinology, Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3335 7850
Email
Farzadnajafipour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Farzad Najafipour
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
خیابان گلگشت، دانشگاه علوم پزشکی تبریز، بیمارستان امام رضا، بخش غدد
City
tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3335 7850
Email
FarzadNajafipour@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Taher Manzary MD

Position

Endocrinology assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Department of Endocrinology, Imam Reza Hospita,
Golgashst street

City

tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 8939

Email

manzarytaher@yahoo.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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total potential data can be shared after
unidentifiable people

When the data will become available and for how long

The access period Starts 3 months after printing the
results

To whom data/document is available

All physicians and scientific researchers

Under which criteria data/document could be used

only for other medical studies

From where data/document is obtainable

Taher Manzary MD, mobile: +98 914 441 6952, Email:
manzarytaher@yahoo.com

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

Initially, you will be asked by e-mail if it is not answered
within 10 days, you will be asked by phone

Comments