

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of levothyroxin on patients with chronic pruritus and positive Anti- TPO

Protocol summary

Summary

This study in a single-blind clinical trial design, aimed to investigate the effects of levothyroxine tablets in patients with chronic pruritus who are Anti TPO antibody positive at the same time. Among the patients referred to the Allergy Clinic with chief complaint of pruritus which lasts at least for 3 menthes in order of matching the inclusion criteria, 72 patients as two groups of 36 subjects will enroll the study. Inclusion criteria included chronic pruritus, Anti TPO antibody positive, age over 20 years and less than 60 years and the main exclusion criteria included a history of taking thyroid medication in the past six months and pregnant women and lactating mothers. The first group will be treated with Levothyroxine and antihistamine tablets while the second group will only be treated with antihistamines. Patients will be treated for 12 weeks and they will be visited once a month during this period to follow healing and treatment effects. Patients healing will be defined as the loss of pruritus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112613612N3**

Registration date: **2015-11-06, 1394/08/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-06, 1394/08/15

Registrant information

Name

Farzad Najafipour

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of levothyroxin on patients with chronic pruritus and positive Anti- TPO

Public title

The effect of levothyroxin on patients with chronic pruritus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with chronic pruritus (over 3 months); patients with positive Anti TPO antibody; patients with 20 to 60 years old ; patients who did not take systemic steroids in the past six months; patients who did not take levothyroxin or methimazole in the past six months. The exclusion criteria: patients younger than 20 years old or older than 60 years; patients who took

systemic corticosteroids, levothyroxin or methimazole in the last six months; lactating mothers or pregnant women.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Sq.

City

Tabriz

Postal code

Approval date

2014-11-13, 1393/08/22

Ethics committee reference number

93117

Health conditions studied

1

Description of health condition studied

chronic pruritus

ICD-10 code

L29.9

ICD-10 code description

Pruritus, unspecified

Primary outcomes

1

Description

Patients pruritus

Timepoint

At baseline and after 3 months of treatment

Method of measurement

Quastionnaire

Secondary outcomes

1

Description

Decrease in severity of pruriency in patient with pruritus and Anti TPO+

Timepoint

After 3 month

Method of measurement

Via VAC questionnaire

Intervention groups

1

Description

In the first group tablet levothyroxin 100 micro gram daily and tablet loratadin 10 milligram daily will be prescribed.

Category

Treatment - Drugs

2

Description

In the second group only tablet loratadin 10 milligram daily will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy Clinic Golgasht infirmary

Full name of responsible person

Dr.Mahnaz Sadeghi Shabestari

Street address

Golgasht St.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Farzad Najafipour

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Daneshgah Square Tabriz

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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

Vice chancellor for research, Tabriz University of Medical Sciences

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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Sadeghi Shabestari

Position

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Position

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Position

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Web page address**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*