

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Therapeutic effect of vitamin D on Hashimoto thyroiditis

Protocol summary

Study aim

Therapeutic effect of vitamin D on Hashimoto thyroiditis

Design

This clinical trial study has two intervention groups. Which samples are selected by an inhomogeneous method.

Settings and conduct

This clinical trial study was performed on 30 samples that were selected by an inhomogeneous method in patients with thyroid problems referring to Amirkola Children's Hospital Endocrinology Clinic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients under the age of 18 with diagnosis of Hashimoto thyroiditis based on laboratory findings and ultrasonography. Exit criteria: Patients with thyroid disease, with or without goiter, with normal levels of antibodies, are excluded. Patients with Hashimoto thyroiditis who were already treated. Patients with thyroid disease with or without goiter have normal levels of autoantibodies. Patients with certain chromosomal syndromes, including Down or Turner. Patients with liver and kidney disease.

Intervention groups

Check and treat low levels of vitamin D.

Main outcome variables

Primary outcome : The therapeutic effects of vitamin D on the level of thyroid autoantibodies in Hashimoto thyroiditis. Secondary outcomes: The therapeutic effects of vitamin D on reducing thyroid gland in Hashimoto thyroiditis.

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20180228038900N1**

Registration date: **2018-04-16, 1397/01/27**

Registration timing: **prospective**

Last update: **2018-04-16, 1397/01/27**

Update count: **0**

Registration date

2018-04-16, 1397/01/27

Registrant information

Name

Morteza Alihanpour Aghamaleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3234 6963

Email address

m.alijanpour@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effect of vitamin D on Hashimoto thyroiditis

Public title

Therapeutic effect of vitamin D on Hashimoto thyroiditis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: All patients under the age of 18 with diagnosis of Hashimoto thyroiditis based on laboratory findings and ultrasonography.

Exclusion criteria:

Exit criteria: Patients with thyroid disease, with or without goiter, with normal levels of antibodies, are excluded. Patients with Hashimoto thyroiditis who were already treated. Patients with thyroid disease with or without goiter have normal levels of autoantibodies. Patients with certain chromosomal syndromes, including Down or Turner. Patients with liver and kidney disease.

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

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**

Ethics Committee of Babol University of Medical Sciences

Street address

Ganjafrooz Street

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2017-11-26, 1396/09/05

Ethics committee reference number

MUBABOL.HRI.REC.1396.55

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

Hashimoto thyroiditis

ICD-10 code

E20-E35

ICD-10 code description

Disorders of other endocrine glands

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

Primary outcome : The therapeutic effects of vitamin D on the level of thyroid autoantibodies in Hashimoto thyroiditis.

Timepoint

Time zero and six months later

Method of measurement

blood test

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

Secondary outcomes: The therapeutic effects of vitamin D on reducing thyroid gland in Hashimoto thyroiditis

Timepoint

Time zero and six months later

Method of measurement

sonography

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

Intervention group: Low levels of vitamin D treatment: First, check blood levels of vitamin D at levels below 30 ng / ml: 1. Low levels of vitamin D between 20 and 30 ng / ml. Pearl contains 50000 units of vitamin D per week for up to 6 weeks, and then checks the blood levels of vitamin D. If the level of vitamin D is increased to above 30 ng, one pearl of vitamin D is given two months until the end of the design (end of 6 months). 2. Low levels of vitamin D lower than 20 ng / ml: Perl vitamin D is 50,000 units per week for one week to 8 weeks and then checks for vitamin D levels. If vitamin levels rise to above 30 ng / ml, Pearl vitamin D is given every month at the end of the plan. Note: If the level of vitamin D does not increase above 30 ng / ml after 6 to 8 weeks in the group, another course of treatment will be performed as described above, and the blood level of vitamin D will be checked again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola Children's Hospital

Full name of responsible person

Morteza Aljanpour aghamaleki

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Ali Akbar Moghaddamnia

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info@mubabol.ac.ir

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Morteza Aljanpour Aghamaleki

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Morteza Aljanpour Aghamaleki

Position

Assistant Professor

Latest degree

Subspecialist

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

-

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available