

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of endothelial dysfunction in hypothyroid neonates that referred to Endocrine & Metabolic Research Center of Isfahan

Protocol summary

Summary

The main purpose of this study is to evaluate endothelial dysfunction in hypothyroid neonates. In this study, ten infants with TSH = 10-50, ten infants with TSH=50-100 and ten infants with serum TSH above 100 are selected. 30 healthy neonates also are selected. From hypothyroid patients before treatment and 4 weeks after treatment with Levothyroxin (10 micrograms per Kg per day) indices of Endothelial Dysfunction is measured. Mean factor levels will be compared before and after therapy in hypothyroid neonates between healthy infants and hypothyroid neonates before treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812153493N1**

Registration date: **2010-05-25, 1389/03/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-05-25, 1389/03/04

Registrant information

Name

Mahin Hashemipour

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 31 1668 5555

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Recruitment status

Recruitment complete

Funding source

Applied Physiology Research Center

Expected recruitment start date

2009-01-19, 1387/10/30

Expected recruitment end date

2010-06-21, 1389/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of endothelial dysfunction in hypothyroid neonates that referred to Endocrine & Metabolic Research Center of Isfahan

Public title

Evaluation of endothelial dysfunction in hypothyroid neonates that referred to Endocrine & Metabolic Research Center of Isfahan

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 2 weeks, Exclusion criteria: Presence of any proven disease, receiving any drug, Small for gestational age infants, presence of Septicemia, presence of inherited metabolic diseases

Age

To **1** year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**
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

Applied Physiology Research Center

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

empty

Ethics committee reference number

287225

Health conditions studied

1

Description of health condition studied

endothelial dysfunction in neonate with hypothyroidism

ICD-10 code

E03

ICD-10 code description

Primary outcomes

1

Description

Von-Willbrand factor

Timepoint

before and 4 weeks after treatment with Levothyroxin

Method of measurement

ELISA

2

Description

ICAM

Timepoint

before and 4 weeks after treatment with Levothyroxin

Method of measurement

ELISA

3

Description

VICAM

Timepoint

before and 4 weeks after treatment with Levothyroxin

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Tablet Levothyroxin 10 micrograms per kg per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine & Metabolic Research Center of Sediqeh

Tahere Isfahan

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Applied Physiology Research Center

Full name of responsible person

Dr. Shaqhaieqh Haqhjoo

Street address

Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Applied Physiology Research Center

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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mahin Hashemipour

Position

Professor Of Pediatric Endocrinology

Other areas of specialty/work

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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