

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of Biotin on blood glucose and plasma lipids in insulin dependent diabetic patients

#### Protocol summary

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##### Summary

Propose of this randomized double blind placebo controlled clinical trial is to evaluate the effect of Biotin on blood glucose and serum lipid concentration in type 1 diabetic patients, therefore 70 insulin dependent diabetic patients (5-25 years old) with poorly controlled (glaciated hemoglobin  $\geq 8\%$ ) were recruited and randomly allocated into two groups. In intervention group, Biotin (40 mcg/kg) was administrated in addition to daily insulin regimen for three months. Laboratory tests including fasting blood sugar, hemoglobin A1C and plasma lipids were measured at the baseline and after 3 months of treatment.

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology of Kermanshah University of Medical Sciences

##### Expected recruitment start date

2008-04-01, 1387/01/13

##### Expected recruitment end date

2009-04-01, 1388/01/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201110027691N1**

Registration date: **2011-11-14, 1390/08/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-11-14, 1390/08/23

##### Registrant information

###### Name

Mitra Hemmati

###### Name of organization / entity

Kermanshah University of Medical Science and Health Service

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1427 6309

###### Email address

##### Scientific title

The effect of Biotin on blood glucose and plasma lipids in insulin dependent diabetic patients

##### Public title

The effect of Biotin on blood glucose and plasma lipids in diabetic patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: HbA1C more than 8% and history of diabetes type 1 for at least one year; age of 5-25 years old. Exclusion criteria : history of renal and cardiac disease, seizure, using corticosteroids or anti-convulsive drugs, also history of hypoglycemic attacks or ketoacidosis during past 3 months, and pregnancy.

##### Age

From **5 years** old to **25 years** old

##### Gender

Both

##### Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Building no. 2, Kermanshah University of Medical Sciences

##### City

Kermanshah

##### Postal code

#### Approval date

2008-03-01, 1386/12/11

#### Ethics committee reference number

87256

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes

#### ICD-10 code

E10

#### ICD-10 code description

Insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

Hg A1C

#### Timepoint

at the baseline and 3 months after intervention

#### Method of measurement

laboratory test (Nycocard kits)

### 2

#### Description

Lipiod profile (cholesterol, triglycerides, low density lipoprotein, high density lipoprotein)

#### Timepoint

before intervention and after 3 months

#### Method of measurement

laboratory method

## Secondary outcomes

### 1

#### Description

advers effects such as hypoglycemia, no tolerance to biotin

#### Timepoint

during the intervention

#### Method of measurement

self monitoring blood sugar by subjects

## Intervention groups

### 1

#### Description

Intervention group: 40 mcg/kg of Biotin, once daily for 3 months

#### Category

Treatment - Drugs

### 2

#### Description

Control group: placebo once daily for 3 months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital

##### Full name of responsible person

Mitra Hemmati

##### Street address

Department of Pediatric, Imam Reza Hospital, Kermanshah University of Medical Sciences

##### City

Kermanshah

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research and Technology of Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Farid Najafei

**Street address**

Shahid Beheshti Blvd.

**City**

Kermanshah

**Grant name**

هزینه پژوهشی دستیاران

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research and Technology of Kermanshah 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**

Kermanshah university of medical sciences

**Full name of responsible person**

Mitra Hemmati

**Position**

assistant professor

**Other areas of specialty/work****Street address**

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**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