

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Effect of Folic Acid on the Endothelial Dysfunction in Children with Diabetes Type 1

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of folic acid on the endothelial dysfunction in children with type 1 diabetes. The study is double blind, placebo-controlled crossover trial. Sixty patients with type 1 diabetes selected and divided in two groups. Each group has 30 people. Folic acid (5 mg) and placebo (produced in Amin Daru factory) was given to each group for 2 months and following a 2 week wash out period cross over was done. Blood samples for endothelial markers (ICAM, VCAM, vWf), lipid profile, FBS and serum folate level will be drawn at 0, 8, 10 and 18 weeks in all of the subjects (before and after drug and placebo). Urine samples are taken for microalbuminuria. Analysis of data will be done by SPSS using ANOVA and t Test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138811033138N1**

Registration date: **2010-05-23, 1389/03/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-05-23, 1389/03/02

##### Registrant information

###### Name

Mohammad Hassan Moaddab

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1223 1263

##### Email address

moadab@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellery of Research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2009-09-23, 1388/07/01

##### 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

Effect of Folic Acid on the Endothelial Dysfunction in Children with Diabetes Type 1

##### Public title

Endothelial Dysfunction in Diabetes Mellitus

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1) Children with diabetes type 1 with at least 1 yr duration. 2) Age >5 yr and < 20 yr. 3) No other systemic diseases. 4) No drug use other than insulin. 5) No hypoglycemia or ketosis during past 48 hr. 6) No smoking. 7) No pregnancy. Exclusion criteria: Uncooperable patient

##### Age

From **5 years** old to **20 years** old

##### Gender

Both

##### Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice Chancellery of research

##### Street address

Isfahan University of Mmedical Sciences

##### City

Isfahan

##### Postal code

#### Approval date

2009-06-09, 1388/03/19

#### Ethics committee reference number

187150

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes Melitus Type 1

#### ICD-10 code

E10

#### ICD-10 code description

Insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

Endothelial dysfunction

#### Timepoint

0, 8, 10, 18 weeks

#### Method of measurement

ICAM, VCAM, vwf

## Secondary outcomes

### 1

#### Description

Lipid profile

#### Timepoint

0, 8, 10, 18 weeks

#### Method of measurement

Triglyceride, cholesterol, HDL-c, LDL-c

### 2

#### Description

Microalbuminuria

#### Timepoint

0, 8, 10, 18 weeks

#### Method of measurement

Urine microalbumin and creatinine

## Intervention groups

### 1

#### Description

Folic acid, 5mg/day, two period of 2 months, cross over

#### Category

Treatment - Drugs

### 2

#### Description

Placebo, 2 period of 2 months, cross over

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Pediatric Endocrinology OPD

##### Full name of responsible person

##### Street address

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor of Research, Isfahan University of Medical sciences

##### Full name of responsible person

Dr Seyed Mohammad Hashemi

##### 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**  
Vice Chancellor of Research, Isfahan 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**

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Isfahan University of Medical Sciences Isfahan

**Full name of responsible person**  
Mohammad Hassan Moaddab, MD

**Position**  
Pediatric Endocrinologist

**Other areas of specialty/work**

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## Person responsible for updating data

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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*