

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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: Uncooperative 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 perod 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

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mohammad Hassan Moaddab, MD

Position

Pediatric Endocrinologist

Other areas of specialty/work

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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