

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of dexamethasone on glucose homeostasis in normal and prediabetic individuals with a first-degree relative with type 2 diabetes

Protocol summary

Summary

OBJECTIVE: The effect of a single 8 mg oral dose of dexamethasone versus placebo on glucose homeostasis, insulin homeostasis, insulin secretion and resistance indices, during oral glucose tolerance test, performed before and 24 hours after dexamethasone. **Inclusion criteria:** 20-65 years old individuals : first-degree relative with type 2 diabetic patients **Exclusion criteria:** corneal wound infection : active liver disease : pregnancy : use of corticosteroids : use of thiazide **Volume of the sample:** 44 individuals with normal oral glucose tolerance test⁴³ : individuals with pre-diabetes. **The intervention:** The effect of a single 8 mg oral dose of dexamethasone, on oral glucose tolerance test. **The time of intervention:** The second day **The primary outcome measurement:** The plasma glucose and insulin measurement in 0, 30, 60 and 120 minutes during oral glucose tolerance test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111308258N1**

Registration date: **2011-12-26, 1390/10/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-26, 1390/10/05

Registrant information

Name

Nader Taheri

Name of organization / entity

Isfahan Endocrine and Metabolism Research Center

Country

Iran (Islamic Republic of)

Phone

+98 31 1335 9933

Email address

emrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan Endocrine and Metabolism Research Center,
Isfahan University of Medical Sciences,

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dexamethasone on glucose homeostasis in normal and prediabetic individuals with a first-degree relative with type 2 diabetes

Public title

Dexamethasone effect on oral glucose tolerance test

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 20-65 years old individuals with first degree relative of diabetic patients **Exclusion criteria:** Active peptic ulcer: active herpetic corneal ulcer: psychosis: positive pregnancy test: current use of oral contraceptives in women and thiazide or glucocorticoids use in any person

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 98

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

Isfahan Endocrine and metabolism Research Center
Ethics Committee

Street address

sedigheh tahereh Medical Research Complex, Khorram
Street, Isfahan, Iran

City

Isfahan

Postal code

8187698191

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

389003

Health conditions studied

1

Description of health condition studied

diabetes mellitus

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Plasma insulin in 0,30,60,120 minutes during OGTT

Timepoint

first day and second day

Method of measurement

pmol/l

2

Description

Plasma glucose in 0,30,60,120 minutes during OGTT

Timepoint

first day and second day

Method of measurement

mmol/l

Secondary outcomes

1

Description

AUC(g)=Area under the curve of glucose

Timepoint

first day and second day

Method of measurement

By related formulae

2

Description

AUC(i)= Area under the curve of insulin

Timepoint

first day and second day

Method of measurement

By related formulae

3

Description

AUC(i) / AUC(g)

Timepoint

first day and second day

Method of measurement

By related formulae

4

Description

HOMA-IR index

Timepoint

first day and second day

Method of measurement

By related formula

5

Description

Homa-B index

Timepoint

first day and second day

Method of measurement

By related formulae

6

Description

Matsuda index

Timepoint

first day and second day
Method of measurement
By related formulae

7

Description
Insulinogenic index
Timepoint
first day and second day
Method of measurement
By related formulae

8

Description
Disposition index
Timepoint
first day and second day
Method of measurement
By related formulae

Intervention groups

1

Description
A single oral 8 mg placebo tablet one time First day
Category
Placebo

2

Description
A single oral 8 mg dexamethasone tablet one time first day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Endocrine and Metabolism Research Center
Full name of responsible person
Dr. Nader Taheri
Street address
Sedigheh Tahereh Medical research complex,
Khorram Street
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person

Dr. Massoud Amini
Street address
Sedigheh Tahereh Medical Research Complex,
Khorram street

City
Isfahan

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

Yes

Title of funding source
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 Endocrine and metabolism research center
Full name of responsible person
Dr. Massoud Amini

Position
Director

Other areas of specialty/work

Street address
Sedigheh Tahereh Medical Research Complex,
Khorram Street

City
Isfahan

Postal code
8187698191

Phone
+98 31 1335 9933

Fax

Email
emrc@mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan Endocrine and Metabolism Research Center
Full name of responsible person
Dr. Massoud Amini

Position
Director and internist

Other areas of specialty/work

Street address
Sedigheh Tahereh Medical Research Complex,

Khorram Street
City
Isfahan
Postal code
8187698191
Phone
+98 31 1335 9933
Fax
Email
emrc@mui.ac.ir
Web page address

Isfahan
Postal code
8187698191
Phone
+98 31 1335 9933
Fax
Email
nader_taheri2002@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan Endocrine and Metabolism Research Center
Full name of responsible person
Dr. Nader-Taheri
Position
Endocrinologist
Other areas of specialty/work
Street address
Sedigheh Tahereh Medical Research Complex,
Khorram street,
City

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