Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 measurment 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

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Isfahan Endocrine and Metabolism Research Center
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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 durig 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
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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
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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
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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