Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Homocysteine,C-reactive protein, and counter regulatory hormone changes in insulin-induced hypoglycemia.

Protocol summary

Summary

Drug-induced hypoglycemia is a major obstacle for individuals with type 1 and type 2 diabetes trying to achieve glycemic targets. The episodes of hypoglycemia may increase cardiovascular mortality among patients with or without underlying heart disease. The mechanisms by which hypoglycemia cause increased cardiovascular risk are not clear and are under debate. According to some studies, hyperglycemia increase blood homocysteine and C-reactive protein (CRP) levels as the predisposing factors of cardiovascular disease. However, the effect of hypoglycemia on the level of CRP and homocysteine markers has not been clarified. To determine whether the episodes of hypoglycemia are likely to be associated with cardiovascular disease by increasing blood CRP and homocysteine concentrations, we carried out a study to evaluate blood levels of these two factors in response to insulin-induced hypoglycemic stress. In this regard, fifteen non-diabetic healthy male individuals were enrolled for the study. In all subjects, hypoglycemia was induced by the injection of 0.1 to 0.15 unit/kg intravenous regular insulin. When a blood glucose level dropped below 45 mg/dl, hypoglycemia would be defined to be present. Blood samples were taken from a dedicated intravenous line before the start of test and serially after the injection of insulin in divided times and for 240 minutes. Counter regulatory hormone levels (growth hormone, cortisol, norepinephrine, epinephrine, ACTH), homocysteine, and CRP would be checked at baseline and 30, 45, 60, 120, 240 minutes after insulin injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811112587N3**
Registration date: **2010-06-01, 1389/03/11**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2010-06-01, 1389/03/11

Registrant information

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Parviz Hosseini
Name of organization / entity
Parsroos Company
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Endocrinology and Metabolism Research Center

Expected recruitment start date

2008-10-01, 1387/07/10

Expected recruitment end date

2008-12-01, 1387/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Homocysteine,C-reactive protein, and counter regulatory hormone changes in insulin-induced hypoglycemia.

Public title

Cardiovascular side effects of hypoglycemia

Purpose

Other

Inclusion/Exclusion criteria

Inclusions Criteria: age 18–65 years, healthy individuals according to clinical and paraclinical assessments, BMI range of 19-30 kg/m2, written informed consent.
Exclusions Criteria: anemia (hematocrit <30%), history of smoking, chronic disease, (i.e. chronic liver disease, renal insufficiency (creatinin > 1.5 mg/dl), and cardiovascular disease), central nervous system diseases including seizure disorder, defined diabetes mellitus, hypertension, concurrent infection, and fasting blood glucose≥126 mg/dl.

Age
From **19 years** old to **40 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Endocrinology and Metabolism Research Center ethics committee

Street address
Shariati Hospital, North Kargar Ave, Tehran 14114, Iran

City
Tehran

Postal code

Approval date
2008-09-28, 1387/07/07

Ethics committee reference number
E-0068

Health conditions studied

1

Description of health condition studied
Homocystein, CRP and counter regulatory hormones evaluations in response to hypoglycemia

ICD-10 code
-

ICD-10 code description
-

Primary outcomes

1

Description
Serum homocystein level

Timepoint
Baseline, and 30, 45, 60, 120, 240 after insulin injection

Method of measurement
Plasma HPLC

2

Description
Serum CRP level

Timepoint
Baseline, and 30, 45, 60, 120, 240 after insulin injection

Method of measurement
Plasma HPLC

Secondary outcomes

1

Description
Blood Growth Hormone Level

Timepoint
Baseline, and 30, 45, 60, 120, 240 minutes after insulin injection

Method of measurement
Plasma HPLC

2

Description
Serum Cortisol

Timepoint
Baseline, and 30, 45, 60, 120, 240 minutes after insulin injection

Method of measurement
Plasma HPLC

3

Description
Serum norepinephrine level

Timepoint
Baseline, and 30, 45, 60, 120, 240 minutes after insulin injection

Method of measurement
Plasma HPLC

4

Description
Serum epinephrine level

Timepoint
Baseline, and 30, 45, 60, 120, 240 minutes after insulin injection
Method of measurement
Plasma HPLC

5

Description
Serum ACTH level
Timepoint
Baseline, and 30, 45, 60, 120, 240 minutes after insulin injection
Method of measurement
Plasma HPLC

Intervention groups

1

Description
Intravenous regular insulin 0.1-0.15 Unit/Kg
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and Metabolism Research Center
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Endocrinology and Metabolism Research Center
Full name of responsible person
Dr. Ramin Heshmat
Street address
5th floor, Shariati Hospital, North Kargar Ave, Tehran 14114, Iran
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Endocrinology and Metabolism Research Center
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
Endocrinology and Metabolism Research Center
Full name of responsible person
Dr. Ramin Heshmat
Position
vice-chancellor/MD,PhD
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Person responsible for updating data

Contact
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Dr. Parviz Hosseini

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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