

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

Name

Parviz Hosseini

Name of organization / entity

Parsroos Company

Country

Iran (Islamic Republic of)

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dr.p.hosseini@gmail.com

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

City

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

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Endocrinology and Metabolism Research Center

Full name of responsible person

Dr. Bagher Larijani

Position

Chancellor of Tehran University of Medical Scieces/MD(Endocrinologist)

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Position

MD

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Web page address**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*