

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Effects of Glucose Insulin Potassium (GIK) infusion on serum Nt.Pro BNP and Hs-CRP levels in patients with acute heart failure

Protocol summary

Summary

The aim of this study is to evaluate the effect of Glucose Insulin Potassium (GIK) solution infusion in acute heart failure (AHF) patients ; by measurement of serum NT-Pro BNP and Highly sensitive C-Reactive Protein (Hs-CRP) levels. In a randomized, controlled, triple-blind clinical trial, 50 patients presented as AHF and referred to emergency department, who had left ventricular ejection fraction (LVEF) < 40% and no diabetes, hypoglycemia, hyperkalemia, and other conditions associated with high CRP level, were divided into two" control and intervention"groups . Serum Nt-pro BNP and Hs-CRP levels were measured and standard therapy for AHF was started in either group at the time of hospital admission. GIK solution including 300 mg/l glucose, 80 meq/l potassium and 50 u/l regular insulin at a rate of 1 cc/kg/h was administered to intervention group (25 persons) during 6 hours from admission and continued for 48 hours later. The placebo (normal saline serum) was administered to the control group (25 persons) by the same volume, rate and time. Serum Nt-pro BNP and Hs-CRP levels were repeated in the 3rd and 5th days of admission in either group .The aforementioned data were recorded in forms and analyzed by statistic methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111238185N1**

Registration date: **2011-12-14, 1390/09/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-14, 1390/09/23

Registrant information

Name

Abolfazl Enaami

Name of organization / entity

Kermanshah university of medical sciences and health services

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Kermanshah university of medical sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-02-19, 1390/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Glucose Insulin Potassium (GIK) infusion on serum Nt.Pro BNP and Hs-CRP levels in patients with acute heart failure

Public title

Effects of Glucose Insulin Potassium infusion on inflammatory markers in patients with acute heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterias: All patients presenting as acute heart

failure with left ventricular ejection fraction (LVEF) < 40% Exclusion criterias: LVEF>40; Diabetes mellitus; Hypoglycemia; hyperkalemia; High Hs-CRP states including Infectious and Rheumatic diseases, cancers, Tissue damages, Burns and inflammatory bowel diseases.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah university of medical sciences

Street address

Kermanshah university of medical sciences, Shahid Beheshti blvd

City

Kermanshah

Postal code

Approval date

2011-11-12, 1390/08/21

Ethics committee reference number

40231

Health conditions studied

1

Description of health condition studied

Acute heart failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

Hs-CRP

Timepoint

Before GIK administration, at 3rd and 5th days after GIK administration

Method of measurement

Blood test

2

Description

Nt Pro BNP

Timepoint

Before GIK administration, at 3rd and 5th days after GIK administration

Method of measurement

Blood test

Secondary outcomes

1

Description

Inhospital death

Timepoint

During hospital-stay period

Method of measurement

On the basis of vital sign

2

Description

Ventricular arrhythmias

Timepoint

During hospital-stay period

Method of measurement

On the basis of cardiac monitoring

Intervention groups

1

Description

Intervention group: 1 cc/kg/h GIK solution with formula 300 g/l glucose, 80 meq/l potassium, 50 u/l insulin during 48h.

Category

Treatment - Drugs

2

Description

Control group: placebo-serum isotonic solution with equal volume and speed

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali hospital

Full name of responsible person

Abolfazl Enaami-Resident of cardiology

Street address

Imam Ali hospital, Shahid Beheshti blvd ,Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology,
Kermanshah university of medical sciences

Full name of responsible person

Dr. Farid Najafi

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Kermanshah university of medical sciences, Shahid
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research and technology,
Kermanshah 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

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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