

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparison of effect of tight and acceptable glycemic control on the rate of Acute rejection in nondiabetic patient after renal transplant

#### Protocol summary

##### Summary

This study is designed to determine the effect of tight blood sugar control in nondiabetic patient after kidney transplantation on graft function. This is a single blind study. Our study population will include patients with 18-70 years old, non-diabetic, without prior transplantation that undergoing deceased donor renal transplantation or living donor transplantation. Patients, after transplantation, were randomly allocated in two groups. In interventional group, Blood sugar (BS) is checked with glucometer after kidney transplantation in recovery room and every 2 hours. Infusion of regular insulin is started when BS is more than 140 mg/dl and continue for 48 hours. After 48 hours, BS checks every 6 hours. If BS is more than 150 mg/dl subcutaneous insulin is given. In control group, BS checks every 6 hours. If BS is more than 150 mg/dl subcutaneous insulin is given. Then the prevalence of kidney rejection, Infections (urinary tract, pneumonia, site of surgery infection) and mortality is compared in two groups in one month after transplantation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012123011938N1**

Registration date: **2013-01-25, 1391/11/06**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-01-25, 1391/11/06

##### Registrant information

###### Name

Jila Rahmania

##### Name of organization / entity

Ahvaz Jondi Shapoor University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 79 1333 0341

##### Email address

rahmania.j@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jondishapour University of Medical Science.

##### Expected recruitment start date

2012-03-19, 1390/12/29

##### Expected recruitment end date

2013-03-19, 1391/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of effect of tight and acceptable glycemic control on the rate of Acute rejection in nondiabetic patient after renal transplant

##### Public title

The effect of insulin infusion for tight glucose control on acute kidney rejection.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria :The End stage renal disease patient  
exclusion criteria:Diabetic patient;Patients lesser than 18years of age;Patients more than 70 years of age

##### Age

From **18 years** old to **70 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

AhvazJoundi Shapoor University of Medical Science

##### Street address

AhvazJoundi Shapoor University of Medical  
Science,Golestan

##### City

Ahvaz

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

eth650

## Health conditions studied

### 1

#### Description of health condition studied

kidney transplant rejection

#### ICD-10 code

T86.1

#### ICD-10 code description

Kidney transplant failure and rejection

## Primary outcomes

### 1

#### Description

Acute kidney rejection

#### Timepoint

First month after transplant

#### Method of measurement

Creatine measurement

## Secondary outcomes

### 1

#### Description

Dialysis

#### Timepoint

First week after transplantation

#### Method of measurement

Creatinin measurement

### 2

#### Description

Hypoglyseemia

#### Timepoint

While insulin infusion

#### Method of measurement

Checking blood suger

### 3

#### Description

Infection

#### Timepoint

First month after transplantation

#### Method of measurement

Chest X ray, Urine analysis, Stool exam,

## Intervention groups

### 1

#### Description

Blood sugar(BS) is checked every 2 hours after kidney transplantation. Infusion of regular insulin is started when BS is more than 140 mg/dl and continue for 48 hours. If BS 141-149 mg/dl insulin infusion 1.5 Unit per hour, BS 150- 179 mg/dl 2U insulin, BS 180- 209 mg/dl 3U insulin, BS 210- 239 mg/dl 4U insulin, BS 240- 269 mg/dl 5U insulin, BS 270-299 mg/dl 6U insulin, BS 300- 329 mg/dl 7U insulin, BS 330- 359 mg/dl 8U insulin, BS >360 mg/dl 12 U insulin. After 48 hours, BS checks every 6 hours. If BS is more than 150 mg/dl subcutaneous insulin is given. 2 U insulin per 50 mg glucose over 150 mg.

#### Category

Treatment - Drugs

### 2

#### Description

Blood sugar(BS) is checked every 6 hours after kidney transplantation. If BS is more than 150 mg/dl subcutaneous insulin is given. 2 U insulin per 50 mg glucose over 150 mg.

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Transplant Department, Golestan Hospital, Ahvaz

**Full name of responsible person**

Jila Rahmanian,MD

**Street address**

Golestan Hospital, Golestan

**City**

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research deputy of JondiShapourAhvaz University of Medical Sciences

**Full name of responsible person**

Jila Rahmanian,MD

**Street address**

Ahvaz Joundi Shapoor University of Medical Science,Golestan

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research deputy of JondiShapourAhvaz 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**

Ahvaz Jondi Shapor University of Medical Science

**Full name of responsible person**

Jila Rahmanian,MD

**Position**

Resident of internal medicine

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Seyed Peyman Payami,MD

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Endocrinologist

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## Person responsible for updating data

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**Other areas of specialty/work**

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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*