

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The efficacy of cold ischemic therapy in the results of transplantation of renal insufficiency by assessing the level of Ngal (neutrophilic gelatinase-dependent lipocalin) in the venous kidney

#### Protocol summary

##### Study aim

1. Determine the efficacy of cold ischemic therapy in the results of transplantation of patients with renal insufficiency

##### Design

The study group is a candidate for renal transplantation from either a live or a cadaver. The sample size is 30. Clinical trial without control, the allocation is single arm, without blindness

##### Settings and conduct

30 patients undergoing transplantation during 1397-1398 are studied. After removing the kidney from the body, the kidney enters normal saline and ice, and cold ischemia begins and until the stage of ischemic transplantation cold is continued. This time varies from person to person, depending on how much the kidney transplant and receptor are. A cold ischemic period is noted for each person. During renal transplantation surgery after anastomosis, 5 minutes after removal of arterial clamp, blood sample renal renal vein is taken immediately and direction.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: In this plan 30 transplant patients in the period from 1397-98 who received either live birth or a member of the cadaver are enrolled in the study, and the criteria for non-entry will not be defined in this study.

##### Intervention groups

After removing the kidney from the bodybuilder, the kidney enters normal saline and ice, and cold ischemia begins and continues until the stage of cold ischemic transplantation continues. A cold ischemic period is noted for each person. During renal transplantation surgery, after anastomosis of the arteries and kidney vein, 5 minutes after removing arterial clamp, a blood sample of renal vein renal transplanted, and for monitoring the venous NGAL level, keeping the principles intact to the lab and will be tested (ELISA).

#### Main outcome variables

1. The amount of Ngal in the blood of the recipient prior to surgery and its rate in intravenous venous renal transplantation during surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131218015841N4**

Registration date: **2018-10-02, 1397/07/10**

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

Last update: **2018-10-02, 1397/07/10**

Update count: **0**

##### Registration date

2018-10-02, 1397/07/10

##### Registrant information

##### Name

Gholamreza Pourmand

##### Name of organization / entity

Urology Research Center, Tehran University of Medical Sciences, Tehran, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8560

##### Email address

pourmand@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2019-05-22, 1398/03/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
The efficacy of cold ischemic therapy in the results of transplantation of renal insufficiency by assessing the level of Ngal (neutrophilic gelatinase-dependent lipocalin) in the venous kidney  
**Public title**  
Evaluating Investigating the role of cold ischemic time in kidney transplantation results by measuring Ngal blood transfusion vein blood sample  
**Purpose**  
Prevention  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients who are candidates for transplantation during the period from 1398 to 1397  
**Exclusion criteria:**  
**Age**  
No age limit  
**Gender**  
Both  
**Phase**  
N/A  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **30**  
**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

Vice chancellor in Research ,Tehran University of Medical Sciences

##### Street address

Emam Khomeini St

##### City

Tehran  
**Province**  
Tehran  
**Postal code**  
1136746911  
**Approval date**  
2018-06-22, 1397/04/01  
**Ethics committee reference number**  
IR.TUMS.VCR.REC.1397.173

## Health conditions studied

### 1

#### Description of health condition studied

Kidney Transplantation

#### ICD-10 code

N19

#### ICD-10 code description

Unspecified kidney failure

## Primary outcomes

### 1

#### Description

Measure the level of Ngal(Neutrophil Gelatinase Associated Lipocalin) blood transfusion venous blood

#### Timepoint

1-before the kidney Transplant 2-During surgery after anastomosis of the artery and vein

#### Method of measurement

Through Eliza's method

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this project, 30 patients undergoing a live or cadaver-bonded transplant candidate undergo a renal renal vein 5 min after surgery for arterial anastomosis and kidney vein, 5 minutes after arterial clamping, and to measure venous NGAL levels With Ngal Crystal Day Kit , The laboratory is transmitted and ELISA is measured by the amount of lipocalin dependent on neutrophil gelatinase.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sina Hospital

**Full name of responsible person**

Dr.Masoud Khalili

**Street address**

Emam Khomeini St

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8560

**Email**

masoudkhalili565@gmail.com

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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masoudkhalili656@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.MohammadAli Sahraeian

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Enghelab St

**City**

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**Phone**

+98 21 8163 3627

**Email**

farzaneh.bagherpour@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.masoud Khalili

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

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Gholamreza Pourmand

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

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gh\_pourmand@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Farzaneh Bagherpour

**Position**

Laboratory expert

**Latest degree**

Bachelor

**Other areas of specialty/work**

Laboratory Medicine

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available