

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 during1397-1398are 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 clam,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 clampus, 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)

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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

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Position

resident

Latest degree

Specialist

Other areas of specialty/work

Urology

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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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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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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