

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparing fluid therapy guided by PVI (Plethysmography Variability Index) monitoring vs. conventional fluid therapy in improving transplant kidney function and blood lactate levels in kidney transplant patients

#### Protocol summary

##### Summary

In a prospective controlled double blinded clinical trial we try to find which method; PVI guided fluid therapy or conventional methods, helps keep kidney function better (as measured by urine output) and prevents acidosis from worsening (as measured by serum lactate). We select our patients from Kidney transplant recipients between 18 and 70 years old who are not cases of Known Cardiomyopathy; AF Rhythm; blood transfusion during surgery; History of valve replacement surgery; Asthma or COPD; Morbid Obesity; EF<40%, Hb<7; Symptomatic coronary artery disease and prior kidney transplantation history. Patients who develop arrhythmias during perioperative period or have a blood loss more than 1000cc are excluded from the study. We use PVI monitoring to give fluids to patients during surgery and use known conventional liberal methods for the control group. We measure Urine volumes, Serum lactate, Hemodynamic measures (heart rate and Mean arterial pressure) and ABG factors during peri-operative period and kidney function 6 months after surgery to compare the newly discovered and non-invasive PVI monitoring to conventional more liberal methods.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016072929116N1**  
Registration date: **2016-12-07, 1395/09/17**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-07, 1395/09/17

#### Registrant information

##### Name

Fardad Iranidoust Haghighi

##### Name of organization / entity

Tehran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2235 2772

##### Email address

f-iranidoosth@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Tehran University of Medical Sciences. School of medicine

#### Expected recruitment start date

2015-09-23, 1394/07/01

#### Expected recruitment end date

2017-03-18, 1395/12/28

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing fluid therapy guided by PVI (Plethysmography Variability Index) monitoring vs. conventional fluid therapy in improving transplant kidney function and blood lactate levels in kidney transplant patients

#### Public title

Comparing fluid therapy for kidney transplant surgery guided by PVI (Plethysmography Variability Index) monitoring and conventional fluid therapy in improving transplant kidney function

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Kidney transplant recipients between 18 and 70 years old who are not cases of known cardiomyopathy; AF rhythm; Blood transfusion during surgery; History of valve replacement surgery; History of asthma or chronic obstructive pulmonary disease; Morbid obesity; EF<40%, Hb<7; Symptomatic coronary artery disease; Prior kidney transplantation history; Exclusion criteria: peri-operative arrhythmias; peri-operative blood loss more than 1000cc;

## 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: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Individuals are assigned to control and intervention group randomly via a random numbers table.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University Of Medical Sciences Medical Ethics Committee

##### Street address

Tehran University Of Medical Sciences, Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2016-04-04, 1395/01/16

#### Ethics committee reference number

IR.TUMS.REC.1395.2281

## Health conditions studied

### 1

#### Description of health condition studied

End Stage Renal Failure

#### ICD-10 code

N18.5

#### ICD-10 code description

End stage kidney disease on dialysis

## Primary outcomes

### 1

#### Description

Urine Volume

#### Timepoint

Before and after aortic declamping, 2hours after surgery, The day after surgery, 6 months after surgery

#### Method of measurement

Reading the Urine bag value

### 2

#### Description

Serum Lactate

#### Timepoint

Before and after aortic declamping, 2hours after surgery, The day after surgery, 6 months after surgery

#### Method of measurement

Arterial Blood Gas sample

## Secondary outcomes

### 1

#### Description

Serum creatine

#### Timepoint

before surgery, The day after surgery

#### Method of measurement

Biochemistry Lab test

### 2

#### Description

Blood Urea Nitrogen

#### Timepoint

before surgery, The day after surgery

#### Method of measurement

Biochemistry Lab test

### 3

#### Description

Arterial Blood Gas (ABG)

#### Timepoint

before surgery, before and after aortic declamp, 2hours after surgery, The day after surgery

#### Method of measurement

Arterial Blood Gas sampling

#### 4

##### **Description**

Heart Rate per minute

##### **Timepoint**

before surgery, before and after aortic declamp, 2hours  
after surgery, The day after surgery

##### **Method of measurement**

Pulse oximetry

#### 5

##### **Description**

Blood Pressure (Mean Arterial Pressure)

##### **Timepoint**

before surgery, before and after aortic declamp, 2hours  
after surgery, The day after surgery

##### **Method of measurement**

Non Invasive Blood Pressure monitoring

### **Intervention groups**

#### 1

##### **Description**

In the intervention group we use PVI monitoring (plethysmography variability index) to administer fluids during kidney transplantation surgery. We use the Masimo set PVI monitoring. Masimo, Irvine California. We use the device to guide the peri-operative fluid therapy during the surgery in the operating room. The PVI index is maintained between 10-13 by administering additional crystalloids. as the index rises above 13, 200 milliliters of crystalloids are administered and maintenance is given so that the index is always between 10 and 13. If the index is below 10, then all the crystalloids are held except half the maintenance need.

##### **Category**

Treatment - Other

#### 2

##### **Description**

In the control group we administer fluids to the patients by the conventional liberal methods for transplant recipient patients. we give fluids freely to compensate for hemodynamic abnormalities and/or fluid loss and deficits and half the maintenance needs to the patients during surgery.

##### **Category**

Treatment - Other

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Shariati Hospital

###### **Full name of responsible person**

Dr. Fardad Iranidoost Haghighi

###### **Street address**

Shariati Hospital, Jalal-e-ale ahmad St, Tehran

##### **City**

Tehran

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Vice Chancellor for research of Tehran University of  
Medical Sciences

###### **Full name of responsible person**

Dr. Shahin Akhonzadeh

###### **Street address**

Poursina St. 16th Azar St. School of medicine. Tehran  
University of Medical Sciences

###### **City**

Tehran

###### **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 of Tehran 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**

Tehran University Of Medical Sciences

###### **Full name of responsible person**

Fardad Iranidoost Haghighi

###### **Position**

Resident of Anesthesiology

###### **Other areas of specialty/work**

###### **Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*